Not for Publication

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CURIA IP HOLDINGS, LLC, **Plaintiff,** **v.** **SALIX PHARMACEUTICALS, LTD., *et al.*,** **Defendants.**	**Civil Action No. 21-19293 (ES) (JRA)** **OPINION**

SALAS, DISTRICT JUDGE

Plaintiff Curia IP Holdings, LLC brought this patent infringement suit against Defendants Salix Pharmaceuticals, Ltd.; Salix Pharmaceuticals, Inc.; Bausch Health Companies, Inc.; Alfasigma S.p.A.; and Alfasigma USA, Inc. (together "Defendants") alleging infringement of U.S. Patent No. 9,186,355 (the "'355 Patent"), No. 10,556,915 (the "'915 Patent"), No. 10,745,415 (the "'415 Patent"), and No. 10,961,257 (the "'257 Patent"). (D.E. No. 69 ("Am. Compl.") ¶¶ 77–113). Before the Court is the parties' request for claim construction with respect to terms in all four patents. (D.E. No. 79 ("Def Open. Br."); D.E. No. 80 ("Pl. Open. Br."); D.E. No. 93 ("Def. Resp. Br."); D.E. No. 95 (Pl. Resp. Br."). The Court held a *Markman* hearing on April 27, 2023. (D.E. No. 135). This Opinion sets forth the Court's constructions of the disputed terms.

I. BACKGROUND

A. Technology Overview

In October 2021, Plaintiff Curia IP Holdings, LLC brought this patent infringement suit against Defendants Salix Pharmaceuticals, Ltd.; Salix Pharmaceuticals, Inc.; Bausch Health Companies, Inc.; Alfasigma S.p.A.; and Alfasigma USA, Inc. (D.E. No. 1). Plaintiff alleges

infringement of the following four patents: the '355 Patent, the '915 Patent, the '415 Patent, and the '257 Patent (together the "patents in suit"). (*See* Am. Compl. ¶¶ 77–113). The patents in suit contain claims directed to mixtures of polymorphic forms of the antibiotic rifaximin, pharmaceutical compositions comprising the same mixtures, and methods of treatment for administering those rifaximin mixtures and pharmaceutical compositions. (*See generally* D.E. No. 79-2, Ex. 1 ("'355 Patent") to D.E. No. 79-1 ("Weisbruch Decl."); D.E. No. 79-3 Ex. 2, ("'915 Patent") to Weisbruch Decl.; D.E. No. 79-4, Ex. 3 ("'415 Patent") to Weisbruch Decl.; D.E. No. 79-5, Ex. 4 ("'257 Patent") to Weisbruch Decl.; Am. Compl. ¶¶ 36–40).

Rifaximin is an antibiotic with a low gastrointestinal ("GI") absorption. ('355 Patent at 4:6–8; '915 Patent at 1:24–31; '415 Patent at 1:26–33; '257 Patent at 1:26–33; D.E. No. 79-16 "Myerson Decl.") ¶ 47). Because it is poorly absorbed into the bloodstream, rifaximin acts locally in the GI tract and can be used in therapy for the treatment of GI infections such as traveler's diarrhea and hepatic encephalopathy. ('915 Patent at 1:24–31; *see also* D.E. No. 79-9, Ex. 8 to Weisbruch Decl. at 1074). Like other active pharmaceutical ingredients ("APIs"), rifaximin can exist in numerous crystalline forms, referred to as polymorphs. (*See, e.g.,* '915 Patent at 1:58–67; D.E. No. 80-4 ("Swift Decl.") ¶ 44). While polymorphs share the same chemical composition, they possess different three-dimensional packing arrangements based on the configuration of individual molecules within their crystal structure. ('355 Patent at 3:40–46; Swift Decl. ¶ 44). Different polymorphs can exhibit different properties—including chemical and physical stability—because of their distinct three-dimensional packing arrangements. (Swift Decl. ¶ 46; Myerson Decl. ¶ 39). These different properties are significant to pharmaceutical manufacturers because they can affect the handling properties and ease with which a drug can be formulated, as well as the stability and bioavailability of the drug product. (Swift Decl. ¶ 46; Myerson Decl. ¶ 40). For

example, as the specification of the '355 Patent explains, "different crystalline polymorphs of an organic compound can display differing physical properties, such as rate of dissolution, which can be important in the formulation of the compound for use as a medicinal substance." ('355 Patent at 3:65–4:2). The specifications of the patents in suit identify at least the following polymorphic forms of rifaximin: α, β, γ, ε, δ, ζ, η, α dry, ι, κ, and θ. ('355 Patent at 1:55–2:45; '915 Patent at 1:58–67; '415 Patent at 1:60–67; '257 Patent at 1:60–67).

Because different polymorphic forms of an API exhibit different chemical and physical properties, pharmaceutical manufacturers often wish to characterize the crystalline form(s) of an API to determine its structure and physical properties. (Swift Decl. ¶¶ 46 & 49). X-ray diffraction ("XRD" or "DRX") is the primary analytic technique for characterizing the structure of crystalline forms of APIs. (*Id.* ¶ 49; Myerson Decl. ¶ 41). XRD experiments can be carried out on single crystals or on polycrystalline powdered samples. (Swift Decl. ¶ 53). When performed on powders, this technique is known as X-ray powder diffraction ("XRPD" or "PRXD"). (Myerson Decl. ¶ 41; Swift Decl. ¶ 54). XRPD is performed by exposing a crystalline powder sample to X-rays of a certain wavelength. (Myerson Decl. ¶ 42; Swift Decl. ¶ 54). When X-rays are directed at a crystalline sample, they are diffracted by the atoms contained within the sample at a unique set of "scattering angles" which differ in their intensities based on the type and arrangements of atoms and molecules in the sample. (Swift Decl. ¶ 53). An instrument known as an X-ray diffractometer measures the intensity of the X-rays that diffract across a range of angles. (*Id.* ¶¶ 50 & 53; Myerson Decl. ¶ 44). The output of an XRPD experiment is typically reported as a graphical pattern known as a diffractogram, where the x-axis plots the scattering angle of the diffracted X-ray beam in terms of 2θ ("two theta" or "2theta") given in units of degrees, and the y-axis plots the intensity of the diffracted X-ray beam either in absolute units, or relative units as compared to the most intense

peak in the diffractogram. (Swift Decl. ¶ 55; Myerson Decl. ¶¶ 44–45). A sample diffractogram taken from the '915 Patent is reproduced below.

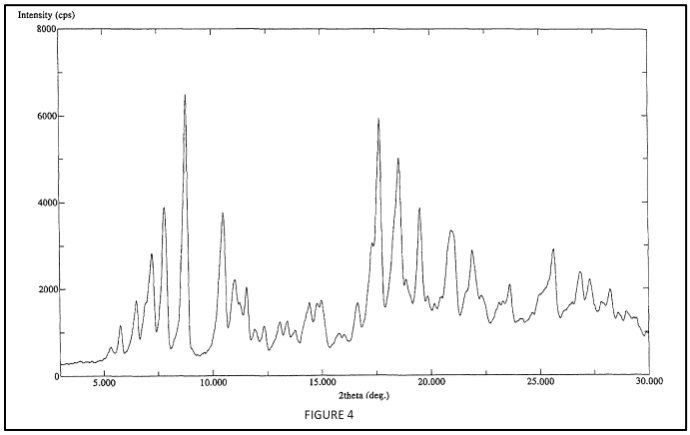

FIGURE 4

('915 Patent, Figure 4). Each crystalline compound has a unique diffraction pattern, analogous to a "fingerprint." (Swift Decl. ¶ 57 (citing D.E. No. 80-16, Ex. L. ("USP 941") to Swift Decl.)). And the diffraction pattern of an unknown sample can be compared to other samples or standard reference patterns of known compounds, to identify the sample. (*Id.* ¶¶ 51 & 57).

B. The '355 Patent

The '355 Patent is entitled "Rifaximin Crystalline Forms and Methods of Preparation Thereof" and issued on November 17, 2015. ('355 Patent Face Page). It is generally directed to a "composition comprising mixed crystalline polymorphs rifaximin α and rifaximin β." ('355 Patent Abstract). The parties only dispute the construction of Claim 1 and Claim 3 in the '355 Patent, which read as follows:

> 1. A rifaximin composition comprising mixed crystalline polymorphs rifaximin α and rifaximin β containing about 3-12% (w/w) of the rifaximin β crystalline polymorph in mixture with a remaining percentage of the rifaximin α crystalline polymorph and from about 2% to about 5% by weight water relative to the weight of the total composition wherein the aqueous dissolution rates of the α and β forms provide a fast acting portion and a slow acting portion of rifaximin antibiotic.
>
> 3. A pharmaceutical composition suitable for treatment of

> gastrointestinal bacterial infections by oral administration comprising an effective amount of a rifaximin composition of claim 1 and a pharmaceutically acceptable carrier.

('355 Patent at 12:62–13:3 & 13:6–9). The '355 Patent is a part of one patent family with its own distinct patent specification separate from the other three patents in suit.

C. The '915 Patent, '415 Patent, and '257 Patent

The remaining three patents in this case—the '915, '415, and '257 Patents—are part of a second patent family and share a nearly identical patent specification.[1] The '915, '415, and '257 Patents are each entitled "Polymorphic Mixture of Rifaximin and its Use for the Preparation of Solid Formulations" and were issued on February 11, 2020, August 18, 2020, and March 30, 2021, respectively. Each of these patents discloses a "Rifaximin polymorphic mixture of α/β form" that exists in a specific ratio, namely "in a relative ratio of 85/15±3 and a process for its preparation." ('915 Patent Abstract; '257 Patent Abstract; '415 Patent Abstract). While the '915 and '257 Patents are directed to rifaximin mixtures and pharmaceutical compositions comprising the same mixtures, the '415 Patent is directed to methods of treatment for administering those rifaximin mixtures and pharmaceutical compositions. (*See, e.g.,* '915 Patent at 10:50–57; '257 Patent at 10:66–11:3; '415 Patent at 10:64–11:9). The claimed polymorphic α/β rifaximin mixture in the '915 Patent is also characterized by X-ray diffraction with certain characteristic 2theta scattering angle values and relative intensity values. (*See, e.g.,* '915 Patent at 10:50–57). The claimed polymorphic α/β rifaximin mixtures in the '415 and '257 Patents are characterized with certain characteristic 2theta scattering angle values only. (*See, e.g.,* '257 Patent at 10:66–11:3; '415 Patent at 10:64–11:9). Claims 1, 2, and 3 of the '915 Patent are at issue and read as follows:

> 1. A Rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3, characterized by an X-Ray spectrum with characteristic

[1] The '915 Patent is the parent patent in the family, the '257 Patent is a continuation of the '915 Patent, and the '415 Patent is a divisional of the '915 Patent. (*See* '415 Patent Face Page; '257 Patent Face Page).

> 2theta values at (relative intensity): 5.32 (11%), 5.78 (19%), 6.50 (27%), 7.24 (45%), 7.82 (61%), 8.80 (100%), 10.50 (59%), 11.02 (35%), 11.58 (32%), 13.08 (20%), 14.42 (26%), 17.32 (48%), 17.68 (93%), 18.58 (79%), 19.52 (61%), 21.04 (52%), 21.60 (30%), and 21.92 (46%).
>
> 2. A pharmaceutical composition comprising the polymorphic mixture of Rifaximin of claim 1, and a vehicle, excipient, or formulative ingredient.
>
> 3. A tablet, comprising the Rifaximin polymorphic mixture of claim 1 and a film coating.

('915 Patent at 10:50–57, 10:58–60 & 10:61–62). Claims 1, 2, and 10 of the '257 Patent are at issue and read as follows:

> 1. A Rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3, characterized by an X-Ray spectrum with characteristic 2theta values at: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92.
>
> 2. A pharmaceutical composition comprising the polymorphic mixture of Rifaximin of claim 1, and a vehicle, excipient, or formulative ingredient.
>
> 10. A tablet, comprising the Rifaximin polymorphic mixture of claim 1 and a film coating.

('257 Patent at 10:66–11:3, 11:4–6 & 12:10–11). Claims 1, 4, 9, and 12 of the '415 Patent are at issue and read as follows:

> 1. A method of treating a subject suffering from traveler's diarrhea comprising: selecting a subject in need of treatment of traveler's diarrhea; administering to said subject a pharmaceutical composition comprising a therapeutically effective amount of Rifaximin in an α/β polymorphic mixture of 85/15±3 in an amount sufficient to treat the traveler's diarrhea, wherein the Rifaximin α/β polymorphic mixture is characterized by an X-Ray spectrum with characteristic 2theta values at: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92.
>
> 4. The method of claim 1**,** wherein the pharmaceutical composition

> comprises 550 mg of Rifaximin α/β polymorphic mixture of 85/15±3.
>
> 9. A method of treating a subject suffering from hepatic encephalopathy comprising: selecting a subject in need of treatment of hepatic encephalopathy; administering to said subject a pharmaceutical composition comprising a therapeutically effective amount of Rifaximin in an α/β polymorphic mixture of 85/15±3 in an amount sufficient to treat the hepatic encephalopathy, wherein the Rifaximin α/β polymorphic mixture is characterized by an X-Ray spectrum with characteristic 2theta values at: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92.
>
> 12. The method of claim 9**,** wherein the pharmaceutical composition comprises 550 mg of Rifaximin α/β polymorphic mixture of 85/15±3.

('415 Patent at 10:64–11:9, 11:14–16, 11:19–12:9 & 12:15–17). The parties dispute the proper construction of the following nine claim terms:

> "A rifaximin composition" ('355 Patent, Claim 1)
>
> "A pharmaceutical composition" ('355 Patent, Claim 3)
>
> "A Rifaximin polymorphic mixture of α/β form" ('915 Patent, Claim 1; '257 Patent, Claim 1)
>
> "A pharmaceutical composition" ('915 Patent, Claim 2; '257 Patent, Claim 2)
>
> "A tablet, comprising the Rifaximin polymorphic mixture of claim 1" ('915 Patent, Claim 3; '257 Patent, Claim 10)
>
> "a pharmaceutical composition" ('415 Patent, Claims 1, 9)
>
> "the pharmaceutical composition comprises 550 mg of Rifaximin α/β polymorphic mixture" ('415 Patent, Claims 4, 12)
>
> "characteristic 2theta values at (relative intensity): 5.32 (11%), 5.78 (19%), 6.50 (27%), 7.24 (45%), 7.82 (61%), 8.80 (100%), 10.50 (59%), 11.02 (35%), 11.58 (32%), 13.08 (20%), 14.42 (26%), 17.32 (48%), 17.68 (93%), 18.58 (79%), 19.52 (61%), 21.04 (52%), 21.60 (30%), and 21.92 (46%)" ('915 Patent, Claim 1)
>
> "characteristic 2theta values at: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80,

> 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92" ('415 Patent, Claims 1 and 9; '257 Patent, Claim 1)

(*See, e.g.*, Pl. Open Br.; Def. Open. Br. at 1–2)

II. LEGAL STANDARD

The ultimate question of the proper construction of a patent is a question of law. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388–91 (1996)). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). "[T]here is no magic formula or catechism for conducting claim construction." *Id.* at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.* (citation omitted).

The words of a claim are generally given their ordinary and customary meaning, which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id*. at 1313. To determine the ordinary and customary meaning of a disputed term, the court must look to "those sources available to the public that show what a person of skill in the art would have understood [the] disputed claim language to mean." *Id.* at 1314. (internal quotation marks and citation omitted). Thus, the court must "look to the claim language, the specification, the prosecution history, and any relevant extrinsic evidence." *Meyer Intellectual Props. Ltd. v. Bodum, Inc*., 690 F.3d 1354, 1368 (Fed. Cir. 2012) (citation omitted); *see also Vitronics Corp. v. Conceptronic, Inc*., 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("In determining the proper construction of a claim, the court has numerous sources that it may properly utilize for guidance. These sources . . . include both

intrinsic evidence (*e.g.*, the patent specification and file history) and extrinsic evidence (*e.g.*, expert testimony).").

With respect to intrinsic evidence, "the claims themselves provide substantial guidance as to the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314 (citations omitted). Indeed, "the context in which a term is used in the asserted claim can be highly instructive." *Id.* Similarly, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term." *Id.* (citation omitted)

"The claims, of course, do not stand alone. Rather, they are part of 'a fully integrated written instrument,' consisting principally of a specification that concludes with the claims." *Id.* at 1315 (internal citations omitted). As such, the specification "is always highly relevant to the claim construction analysis" and "is the single best guide to the meaning of a disputed term." *Id.* at 1315 (quoting *Vitronics*, 90 F.3d at 1582). Indeed, "the specification necessarily informs the proper construction of the claims" and it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." *Id.* at 1316–17. Notably, however, the court may "not read limitations from the specification into claims." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012). Specifically, the Federal Circuit has "repeatedly warned against confining the claims to . . . embodiments" described in the specification. *Phillips*, 415 F.3d at 1323. Nevertheless, "the specification may reveal a special definition given to a claim term by the patentee" or "may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." *Id.* at 1316; *see also Aventis Pharm. Inc. v. Amino Chems. Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013) ("The written description and other parts of the specification, for example, may shed contextual light on the plain and ordinary meaning; however, they cannot be used to narrow a claim term to deviate from the

plain and ordinary meaning unless the inventor acted as his own lexicographer or intentionally disclaimed or disavowed claim scope."). "Even when guidance is not provided in explicit definitional format, the specification may define claim terms by implication such that the meaning may be found in or ascertained by a reading of the patent documents." *Irdeto Access, Inc. v. Echostar Satellite Corp.*, 383 F.3d 1295, 1300 (Fed. Cir. 2004) (internal quotation marks and citation omitted).

The court should also consider the patent's prosecution history—"the complete record of the proceedings before the [Patent and Trademark Office] . . . includ[ing] the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. Although the prosecution history "often lacks the clarity of the specification and thus is less useful for claim construction purposes," it can nevertheless "inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

Finally, in some cases, courts "will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 574 U.S. at 331. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). Expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Phillips*, 415 F.3d at 1318. Overall, although extrinsic evidence "may be useful to the court," it is "less reliable" than

intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318–19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

III. DISCUSSION

A. Person of Ordinary Skill in the Art

Claims are construed from the vantage point of a person of ordinary skill in the art ("POSA") at the time of the invention. *Phillips*, 415 F.3d at 1313. Thus, before a court can review the disputed claim terms and phrases, it must determine "the level of skill that a POSA possessed at the time of the invention." *Cambria Co. LLC v. Hirsch Glass Corp.*, No. 21-10092, 2022 WL 4031422, at *3 (D.N.J. Sept. 2, 2022).

Here, the parties define a POSA similarly. According to Plaintiff's expert, Dr. Swift,

> the POSA for the patents-at-issue is a scientist with a degree in pharmaceutical science, chemistry, or chemical engineering, and/or materials sciences with the working knowledge of the theory and practice of crystallography, crystal engineering, and pharmaceutical solid state chemistry, including polymorph, salt, and/or co-crystal screening, characterization, and development. The POSA could have a Ph.D. or Master's degree, but a Bachelor's degree in these disciplines coupled with at least five years of practical experience in the field of pharmaceutical solid state chemistry is also sufficient. The POSA may also work in collaboration with other individuals who have experience in pharmaceutical formulation and/or medicinal chemistry, as well as in developing pharmaceutical drug products.

(Pl. Open. Br. at 3–4 (citing Swift Decl. ¶ 30)). While similar to Plaintiff's definition, Defendants propose a definition of a POSA that includes a multi-disciplinary team. According to Defendants' expert, Dr. Myerson,

> [t]he person of ordinary skill in the art would have been a multi-disciplinary team including: (1) a person who would have had a Ph.D. in chemistry,

> chemical engineering, or a related discipline, with a minimum of three years' experience related to powder x-ray diffraction analysis of solid pharmaceutical active ingredients (API) and/or drug products, along with other forms of characterization, testing, and/or evaluation of API and/or drug products; (2) a person who would have had a Ph.D. in chemistry, chemical engineering, pharmacology, or a related discipline with knowledge and/or experience related to the manufacture of solid active pharmaceutical ingredients and the manufacture of drug products; (3) a person who would have had a Ph.D. in chemistry, chemical engineering, pharmacology, biology, molecular biology, or a related discipline with knowledge and/or experience with respect to solid polymorphic forms of chemical compounds, specifically including rifaximin, along with their characterization, testing, properties, and in vivo operation; and (4) a person that would have had (i) a Ph.D. in pharmacology, biology, molecular biology, biomedical science, microbiology, or a related discipline, and/or (ii) a medical degree and board certification in gastroenterology.

(Myerson Decl. ¶ 53).

Though the POSA definitions set forth by the parties in this action differ slightly, there is no suggestion that the differences will impact the Court's construction of the disputed claim terms in this case. And the parties have made no argument as to which definition the Court should adopt. In fact, the parties agreed that the distinction between their proposed definitions would not have any material impact on the outcome of this claim construction. (D.E. No. 145 ("*Markman* Hr'g Tr.") at 9:24–10:13). As such, the Court sees no material difference between the definitions put forth by the parties and finds that its claim construction analyses would be the same under either definition. *Supernus Pharms., Inc. v. TWi Pharms., Inc.*, 265 F. Supp. 3d 490, 496–97 (D.N.J. 2017), *aff'd*, 747 F. App'x 852 (Fed. Cir. 2018).

B. Construction of Agreed-Upon Terms

The Court adopts the following agreed-upon construction:

1. *"[H]ydrated silicon dioxide"* ('415 Patent, Claims 6 & 14; '257 Patent, Claim 7)

Plaintiff	Defendants	The Court
"[S]ilicon dioxide which contains water"	"[S]ilicon dioxide which contains water"	"[S]ilicon dioxide which contains water"

Plaintiff initially disputed Defendants' proposed construction of "hydrated silicon dioxide" (as appearing in the '415 Patent, Claims 6 and 14; and the '257 Patent, Claim 7) as meaning "silicon dioxide which contains water." (*See, e.g.,* Pl. Open. Br. at 38–40). However, on April 20, 2023, Plaintiff wrote to the Court stating that it "agrees to [D]efendants' proposed construction for the claim term 'hydrated silicon dioxide' as meaning 'silicon dioxide which contains water.'" (D.E. No. 123). Plaintiff again confirmed this position at the *Markman* Hearing. (*Markman* Hr'g Tr. at 144:4–10). Accordingly, the Court adopts the parties' agreed-upon construction and need not further provide any construction in relation to "hydrated silicon dioxide" because the agreed-upon construction resolves any dispute in claim scope. *See Vivid Technologies, Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.").

C. Construction of Disputed Terms

The Court sets forth the construction of the disputed claim terms below.

a. Disputed Claim Terms in the '355 Patent

1. *"A rifaximin composition"* ('355 Patent, Claim 1)

Plaintiff	Defendants	The Court
Construction of "A rifaximin composition" is not necessary. To the extent construction is necessary, "A rifaximin composition" is meant to have its plain and ordinary meaning, *e.g.*, "any composition comprising rifaximin."	"A composition comprising mixed crystalline polymorphs rifaximin α and rifaximin β and no other rifaximin polymorphs" ("Defendants' Initial Construction") To the extent a different construction is considered, Defendants would propose: "A composition comprising mixed crystalline polymorphs rifaximin α and rifaximin β, wherein the predominant polymorphs are rifaximin α and rifaximin β, although a certain amount of rifaximin γ (but no other rifaximin polymorphs) may also be present" ("Defendants' Alternative Construction")	"Any composition comprising rifaximin"

The disputed claim term "A rifaximin composition" appears in Claim 1 of the '355 Patent, which reads as follows:

> 1. A rifaximin composition comprising mixed crystalline polymorphs rifaximin α and rifaximin β containing about 3-12% (w/w) of the rifaximin β crystalline polymorph in mixture with a remaining percentage of the rifaximin α crystalline polymorph and from about 2% to about 5% by weight water relative to the weight of the total composition wherein the aqueous dissolution rates of the α and β forms provide a fast acting portion and a slow acting portion of rifaximin antibiotic.

('355 Patent at 12:62–13:3). Plaintiff argues that the context of the claim language and the intrinsic record support a construction of "a rifaximin composition" that encompasses "any rifaximin composition," including mixtures with other polymorphic forms of rifaximin in addition to the α and β forms. (Pl. Open. Br. at 9). In contrast, Defendants argue that the claim language and intrinsic record support a construction of "a rifaximin composition" that includes only the rifaximin α and β polymorphs and no other rifaximin polymorphs. (Def. Open. Br. at 10–17). In the alternative, Defendants argue that, to the extent the Court considers a broader construction, "a rifaximin composition" should be construed to mean "[a] composition comprising mixed crystalline polymorphs rifaximin α and rifaximin β, wherein the predominant polymorphs are rifaximin α and rifaximin β, although a certain amount of rifaximin γ (but no other rifaximin polymorphs) may also be present." (*Id.* at 18–19). Accordingly, the parties' dispute centers around whether "a rifaximin composition" encompasses rifaximin polymorphs other than the α and β forms. For the reasons set forth below, the Court construes "[a] rifaximin composition" to mean "any rifaximin composition."

i. The Intrinsic Record Supports Plaintiff's Construction

In resolving this dispute, the Court begins, as it must, with the words of the claim. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324 (Fed. Cir. 2002). The language of Claim 1 of

the '355 Patent supports an open-ended construction of "a rifaximin composition" that encompasses more than just the rifaximin α and rifaximin β polymorphs. To start, as Plaintiff points out (Pl. Open. Br. at 9–10), the claim in which the disputed term appears uses the transitional phrase "comprising" ('355 Patent at 12:62), which "signals that the entire claim is presumptively open-ended." *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1371 (Fed. Cir. 2005); *Mars, Inc. v. H.J. Heinz Co., L.P.*, 377 F.3d 1369, 1376 (Fed. Cir. 2004) (stating that the transitional term comprising is "open-ended and does not exclude additional, unrecited elements or method steps.") (citing MPEP, 8th ed., rev. 1 § 2111.03 (2003)). Because the patentee invoked this open-ended treatment by using the term "comprising," this portion of the claim language supports a construction of "a rifaximin composition" that encompasses additional unrecited elements such as rifaximin polymorphs other than α and β. *Gillette*, 405 F.3d at 1372 (construing the phrase "comprising . . . a group of first, second, and third blades" in a patent protecting a particular type of safety razor to also encompass four-bladed safety razors). In fact, other courts have held that "[w]hen a patent recites a compound *comprising* a specific polymorphic form, that does not foreclose the possibility that other active ingredients are also present." *Forest Lab'ys, LLC v. Accord Healthcare Inc.*, No. 15-0272, 2016 WL 6892094, at *1 n.6 (D. Del. Nov. 21, 2016) (emphasis added); *In re Armodafinil Patent Litig. Inc.*, 939 F. Supp. 2d 456, 474 (D. Del. 2013) (explaining that the claim term "comprising" allows for other forms of armodafinil to be present in the recited composition).

Other terms in Claim 1 also support an open-ended construction. More specifically, the claim recites "crystalline polymorphs rifaximin α and rifaximin β containing about 3-12% (w/w) of the rifaximin β crystalline polymorph in mixture." ('355 Patent at 12:62–65). Before specifying the percentage of the rifaximin β polymorph, the claim uses the word "containing," which, like

"comprising," is inclusive or "open-ended and does not exclude additional unrecited elements or method steps." *Mars, Inc.*, 377 F.3d at 1376 (citing MPEP, 8th ed., rev. 1 § 2111.03 (2003)). The claim also specifies that the rifaximin β crystalline polymorph is in "mixture," a term that the Federal Circuit has also held does not exclude additional, unnamed ingredients, such as, in this case, rifaximin polymorphs other than α and β. ('355 Patent at 12:62–65); *Mars, Inc.*, 377 F.3d at 1376. Accordingly, claim context supports an open-ended construction and indicates that Claim 1 of the '355 Patent encompasses more than just the rifaximin α and rifaximin β polymorphs.

"The claims, of course, do not stand alone" and the specification "is always highly relevant to the claim construction analysis" and "is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (quoting *Vitronics*, 90 F.3d at 1582). The specification of the '355 Patent, too, supports an open-ended construction of "a rifaximin composition" that encompasses more than just the rifaximin α and rifaximin β polymorphs. To start, the specification consistently uses the word "comprising" when describing the rifaximin composition of the invention. (*See, e.g.*, '355 Patent at Abstract ("The present invention is directed to methods for preparation of a composition *comprising* mixed crystalline polymorphs rifaximin α and rifaximin β.") (emphasis added); *see also id*. at 2:53–55 ("In various embodiments, the invention can provide a method for the manufacture of a composition *comprising* mixed crystalline polymorphs rifaximin α and rifaximin β.") (emphasis added); *id.* at 3:5–6, 3:23–25 & 4:29–30). As discussed above, this supports an open-ended construction which does not exclude additional unrecited rifaximin polymorphs. Further, there are multiple passages in the specification that indicate that Claim 1 of the '355 Patent includes polymorphs other than rifaximin α and rifaximin β in the claimed rifaximin composition. For example, the specification provides:

> It is also possible to obtain X-ray powder diffractograms of the material, which serves to indicate the relative contents of the

> rifaximin α and rifaximin β polymorphs in the final product. *Other rifaximin polymorphs can also be present*, but the predominant polymorphs are the rifaximin α and rifaximin β polymorphs. *It is possible that a certain amount of the relatively amorphous rifaximin γ can also be present*.

(*Id.* at 7:61–8:1) (emphasis added). Additionally, when characterizing one of the embodiments of the rifaximin composition of the invention, the specification states that "[w]hen the water content of the solid reaches the level of between 2.5% and 5.0%, inspection of the X-ray powder diffractogram of the sample can reveal that a mixture of rifaximin α and rifaximin β has been obtained, possibl[y] comprising *additional crystalline polymorphs*." (*Id.* at 8:26–30) (emphasis added). Together, these statements support a construction of "a rifaximin composition" that encompasses more than just the rifaximin α and rifaximin β polymorphs.

Other intrinsic evidence further supports an open-ended construction. More specifically, the specification incorporates by reference a number of prior art patents, including U.S. Patent Number 7,045,620 ("'620 Patent"), Number 7,612,199 ("'199 Patent"), Number 8,158,781 ("'781 Patent"), Number 8,158,644 ("'644 Patent"), and Number 8,193,196 ("'196 Patent"), which disclose crystalline rifaximin polymorphs other than just rifaximin α and β. (*See, e.g.*, '355 Patent at 1:23–26; *id.* at 1:55–57 ("The ['620 Patent] describes crystalline polymorphous forms of rifaximin, named rifaximin α and rifaximin β, and a poorly crystalline form named rifaximin γ."); *id.* at 2:24–38 ("In [the '199 Patent] . . . [t]he polymorph called rifaximin γ is characterized by a powder X-ray diffractogram much poorer because of the poor crystallinity; the significant peaks are at the values of the diffraction angles 2θ of 5.0°; 7.1°; and 8.4°."); *id.* at 2:44–45 ("[The '781 Patent] and ['644 Patent] claim the individual α, β and γ crystalline polymorphs of rifaximin."); *id.* at 1:23–26 (incorporating by reference the '196 Patent which discloses rifaximin polymorphic forms δ and ε.); D.E. No. 80-18, Ex. N. to Swift Decl. ("'196 Patent") at 8:37–9:6). The Federal

Circuit has emphasized that prior art cited in a patent "can have particular value as a guide to the proper construction of [a] term, [and] it may indicate not only the meaning of the term to persons skilled in the art, but also that the patentee intended to adopt that meaning." *V-Formation, Inc. v. Benetton Grp. SpA*, 401 F.3d 1307, 1311 (Fed. Cir. 2005). And when read in context of the claim language and other portions of the specification, these prior art patents, which disclose rifaximin polymorphs other than α and β, constitute relevant intrinsic evidence that indicates the patentee intended to adopt a meaning of "a rifaximin composition" that encompasses more than just the rifaximin α and rifaximin β polymorphs. *See, e.g., V-Formation, Inc.*, 401 F.3d at 1311 (finding that District Court correctly considered a prior art patent cited on face of the patent in construing a disputed term); *Best Med. Int'l, Inc. v. Varian Med. Sys., Inc.*, No. 18-1599, 2020 WL 4192509, at *6 (D. Del. July 21, 2020) (construing "optimizer" to mean a "program or device that *iteratively* attempts to find a preferred solution" based in part on the disclosure of a patent that was incorporated by reference into the patent at issue and which addressed optimization as being iterative) (emphasis added). As such, both claim context and the specification support an open-ended construction of "a rifaximin composition" that does not exclude additional unrecited elements such as rifaximin polymorphs other than α and β.

ii. The Court is not Convinced by Defendants' Contrary Arguments in Support of Their Initial Construction

Defendants' arguments to the contrary and in support of their Initial Construction are unavailing. *First*, Defendants argue that the language of the claim supports a construction which does not include any other rifaximin polymorphs. Defendants argue that "[t]he claim does not mention any other rifaximin polymorphs" and the focus of the claim "is solely on the α and β forms." (Def. Open Br. at 10; Def. Resp. Br. at 2). However, as Plaintiff points out, "[n]ot reciting a claim element is not equivalent to excluding it," particularly since, as described above, the claim

uses a number of terms such as "comprising," "containing," and "mixture" to indicate that it is open-ended. (Pl. Resp. Br. at 5). The Court agrees that this open-ended language does not exclude additional unrecited elements such as rifaximin polymorphs other than α and β simply because other polymorphs were not explicitly listed in Claim 1.

Defendants also contend that "[w]hile the claim recites 'a rifaximin composition comprising mixed crystalline polymorphs rifaximin α and rifaximin β,' it does not recite 'a rifaximin composition comprising a mixture of crystalline polymorphs ***comprising*** rifaximin α and rifaximin β.'" (Def. Open. Br. at 11). More specifically, Defendants argue that the term "comprising" "means the composition can include other ingredients, but the rifaximin portion of [the] composition is defined by the claim to be solely 'mixed crystalline polymorphs rifaximin α and rifaximin β' and no other rifaximin polymorphs." (*Id.*; Def. Resp. Br. at 2). To support their position, Defendants cite to the Federal Circuit's decision in *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1343 (Fed. Cir. 2007) to emphasize that "[c]omprising is not a weasel word with which to abrogate claim limitations." (Def. Resp. Br. at 3–4 (quoting *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1343 (Fed. Cir. 2007)). Defendants argue that because the claim expressly defines the rifaximin portion of the claimed composition as including only the α and β polymorphs, this limitation cannot be abrogated by the use of the term "comprising." (*Id*. at 4). In response, Plaintiff cites to the Federal Circuit's decision in *Gillette*, 405 F.3d at 1372, to argue that there would be no need to recite the term "comprising" twice for the claim to properly be construed as open-ended, because when "comprising" is used as a transitional phrase, it "signals that the entire claim is presumptively open-ended." (Pl. Resp. Br. at 6 (citing *Gillette Co.*, 405 F.3d at 1371)). For the reasons set forth below, the Court agrees with Plaintiff and finds that this case is more analogous to *Gillette* than to *Dippin' Dots*.

The "determination of what is or is not excluded by a transitional phrase must be made on a case-by-case basis in light of the facts of each case." MPEP § 2111.03. In *Gillette*, the patentee claimed a safety razor blade "comprising . . . a group of first, second, and third blades." *Gillette Co.*, 405 F.3d at 1372. After reviewing the intrinsic evidence, the Federal Circuit held that the claim could encompass more than just three-bladed razors. *Id.* at 1371–72. Relevant to the court's conclusion was the fact that the claim used "open" claim terms such as "comprising" to encompass subject matter beyond a razor with only three blades and that the specification made express references to "blade units with a plurality of blades," showing that the invention covered razors with more than three blades. *Id.* at 1371–74. Like in *Gillette*, the Court finds that "a rifaximin composition" encompasses more than just the rifaximin α and rifaximin β polymorphs, based on the fact that the claim uses "open" claim terms such as "comprising," "containing," and "mixture" and that the specification makes express references to other rifaximin polymorphs. (*See, e.g.*, '355 Patent at 12:62–65, 7:61–8:1, 8:26–30, 1:55–57, 2:24–38, 2:44–45 & 1:23–26). As such, the Court finds that it would not be necessary, as Defendants suggest, to recite the term "comprising" twice for the claim to properly be construed as open-ended.[2]

The Federal Circuit's decision in *Dippin' Dots* does not lead this Court to reach a contrary conclusion. In *Dippin' Dots,* the claims at issue recited the term "comprising" to introduce steps in the method for preparing and storing a novelty ice cream product in the form of beads. *Dippin' Dots*, 476 F.3d at 1340. Recognizing that "the written description specifically describe[d] 'beads' as having a 'smooth, spherical appearance"' and that the patentee had argued "that a 'bead' was 'a

[2] In fact, the dissenting opinion in *Gillette* raised this very argument, disagreeing with the majority because "Claim 1 read[] 'comprising a guard, a cap, and a group of first, second, and third blades'; [but did] not read 'a group of blades comprising first, second, and third blades.'" *Gillette Co.*, 405 F.3d at 1376. Nevertheless, the majority in *Gillette* declined to follow this argument, relying instead on the open claim term "comprising" together with the language of the specification to find that the claim could cover a razor with more than three blades. *Id.* at 1371–74. As stated above, a similar conclusion is warranted in this case with respect to Claim 1 of the '355 Patent.

small round ball or round drop,"' the Federal Circuit found no error in the District Court's "limitation of the claim scope to exclude processes that produce[d] irregularly shaped particles." *Id.* at 1343. The Federal Circuit determined that "[t]he presumption raised by the term 'comprising' d[id] not reach into each of the []steps to render every word and phrase therein open-ended—*especially where, as here, the patentee ha[d] narrowly defined the claim term*." *Id.* at 1343 (emphasis added). The Court emphasized that "[c]omprising [wa]s not a weasel word with which to abrogate claim limitations." *Id.* In other words, in "*Dippin' Dots*, the relevant claim term was already 'narrowly defined' during claim construction to exclude specific processes and the appellant sought to rely on 'comprising' to bring those same explicitly excluded processes back within the scope of the claim." *Kom Software, Inc. v. NetApp, Inc.*, No. 2021-1075, 2021 WL 5985360, at *1 (Fed. Cir. Dec. 17, 2021). This case is distinguishable. To start, Plaintiff's proposed construction that encompasses additional rifaximin polymorphs does not abrogate the recited claim limitations that require the β rifaximin polymorph to be present in a specific percentage and that require the rifaximin composition to be from about 2% to about 5% by weight water relative to the weight of the total composition. ('355 Patent at 12:62–67). Nor does it abrogate the claim limitation that requires the aqueous dissolution rates of the α and β forms to provide a fast-acting portion and a slow-acting portion of rifaximin antibiotic. (*Id.* at 12:67–13:3). It simply adds additional unrecited claim elements—other rifaximin polymorphs—as "comprising" is intended to do. *Lundbeck v. Lupin Ltd.*, No. 18-0088, 2021 WL 4944963, at 101 n.24 (D. Del. Sept. 30, 2021). Further, in this case there is no indication in the written description that the patentee narrowly defined the claim term "a rifaximin composition"; in fact, as already described above, there are multiple passages in the specification that indicate that Claim 1 of the '355 Patent includes other polymorphs in the claimed rifaximin composition. (*See, e.g.,* '355

Patent at 1:23–26; 1:55–57, 2:24–38, 2:44–45; 2:53–55, 3:5–6, 3:23–25, 4:29–30, 7:61–8:1 & 8:26–30). As such, unlike in *Dippin' Dots*, Plaintiff is not relying on "comprising" to bring excluded polymorphs back within the scope of Claim 1.[3]

Second, Defendants argue that the specification further confirms that the claimed "rifaximin composition" includes the α and β polymorphs and no other rifaximin polymorphs. (Def. Open. Br. at 11–13; Def. Resp. Br. at 2–3). To start, Defendants contend that "[t]he specification emphasizes throughout that the invention relates to rifaximin compositions that contain a mixture of the α and β polymorphs only and to methods of manufacturing such compositions." (Def. Open. Br. at 11). More specifically, Defendants point to a portion of the specification which states that "[t]he *present invention* is directed, in various embodiments, to methods for the manufacture of mixed crystalline polymorphs rifaximin α and rifaximin β." (*Id.* (quoting '355 Patent at 2:49-51) (emphasis added))). Likewise, they point to a portion of the specification, which states that "[t]he composition comprising mixed crystalline polymorphs rifaximin α and rifaximin β can comprise various ratios of the two polymeric crystalline forms rifaximin α and rifaximin β." (*Id.* at 12 (quoting '355 Patent at 5:10–13). Defendants contend that here again "the specification is addressing *the* composition, namely the composition of the present

[3] Defendants also cite to *Liberty Ammunition, Inc. v. U.S.*, 835 F.3d 1388, 1399 (Fed. Cir. 2016) to support their argument that "comprising" cannot be used as a weasel word with which to abrogate claim limitations. (Def. Resp. Br. at 3–4). The Court, however, finds *Liberty Ammunition, Inc.* distinguishable. In *Liberty Ammunition, Inc.*, which involved a patent directed to a projectile structured to be discharged from a firearm, the patentee claimed "a body including a nose portion and tail portion, said body further including an interface portion disposed intermediate opposite ends of said body." *Liberty Ammunition, Inc.*, 835 F.3d at 1399. Because the claim used the open-ended word "including" before "intermediate opposite ends," the trial court found that "so long as the interface was positioned, in part, between the forward end and the trailing end of the projectile, it did not matter if the interface was also positioned outside of that prescribed area." *Id.* In rejecting the trial court's interpretation, the Federal Circuit stated that "[w]hile the open-ended term 'including' does precede 'intermediate opposite ends,' [t]he trial court's refusal to limit the projectile's interface so that it does not extend all of the way to the forward or trailing ends of the projectile. . . significantly diminishes the 'intermediate opposite ends' limitation, almost to the point of rendering it a nullity" because the very essence of the intermediate opposite ends limitation was to define a precise position. *Id.* In contrast, here, as explained above, Plaintiff's proposed construction that encompasses additional rifaximin polymorphs does not abrogate the recited claim limitations to the point of rendering them a nullity. It simply adds additional unrecited claim elements—other rifaximin polymorphs—as "comprising" is intended to do.

invention, and defining the rifaximin component of the composition as consisting solely of rifaximin α and rifaximin β." (*Id.*). Because the Federal Circuit has made clear that "[w]hen a patentee 'describes the features of the 'present invention' as a whole, he implicitly alerts the reader that 'this description limits the scope of the invention,'" Defendants argue that in these portions of the specification, the inventor limited the rifaximin component of the invention to the rifaximin α and rifaximin β polymorphs only. (*Id.* at 11–12 (quoting *Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1353 (Fed. Cir. 2016)). The Court disagrees.

"Limiting claims from the specification is generally not permitted absent a clear disclosure that the patentee intended the claims to be limited as shown." *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1334 (Fed. Cir. 2007). In some circumstances, "a patentee's consistent reference to a certain limitation or a preferred embodiment as 'this invention' or the 'present invention' can serve to limit the scope of the entire invention, particularly where no other intrinsic evidence suggests otherwise." *Absolute Software, Inc. v. Stealth Signal, Inc.*, 659 F.3d 1121, 1136 (Fed. Cir. 2011). However, "use of the phrase 'present invention' or 'this invention' is not always so limiting, such as where the references . . . are not uniform, or where other portions of the intrinsic evidence do not support applying the limitation to the entire patent." *Id.* at 1136–37. Here, the Court finds that the patent's use of the phrases "present invention" and "the composition" when describing the "mixed crystalline polymorphs rifaximin α and rifaximin β" disclosed in the '355 Patent are not so limiting. As stated already, the specification consistently uses the word "comprising" when describing the rifaximin composition of the invention, including in one of the passages which Defendants assert is limiting. (*See, e.g.*, '355 Patent at 5:10–13). This supports an open-ended construction. (*See also id.* at Abstract, 2:53–55, 3:5–6, 3:23–25 & 4:29–30). Further, there are multiple portions of the specification that reference other rifaximin

polymorphs. (*See, e.g., id.* at 7:61–8:1, 8:26–30, 1:55–57, 2:24–38, 2:44–45, 1:23–26). In fact, Defendants' own alternative construction, which provides that "[a] rifaximin composition" means "[a] composition comprising mixed crystalline polymorphs rifaximin α and rifaximin β, wherein the predominant polymorphs are rifaximin α and rifaximin β, although a certain amount of rifaximin γ (but no other rifaximin polymorphs) may also be present" acknowledges that the patent specification discloses other rifaximin polymorphs in addition to α and β, namely the γ polymorph. (Def. Open Br. at 9).[4] Accordingly, this is not a case where the patentee consistently referenced only the rifaximin α and β polymorphs as "'this invention' or the 'present invention'" such that it limited the scope of the entire invention to only those two polymorphs, and in fact the "intrinsic evidence suggests otherwise." *Absolute Software, Inc.*, 659 F.3d at 1136.

Defendants also argue that the claimed "rifaximin composition" includes the α and β polymorphs and no other rifaximin polymorphs because the specification's focus is solely on mixtures of α and β polymorphs. (Def. Open. Br. at 12). In support of this argument, they point to a portion of the specification which they contend only references the α and β polymorphs, and provides that "[a] pharmaceutical composition useful as [a medication for treatment of infections of the GI tract] can be formulated by combination of Rifaximin mixed α and β polymorphs and a suitable pharmaceutical carrier. The percentage of α and β polymorph of the mixture can be any percentage given above." (*Id.* (citing '355 Patent at 3:28–32) (alterations in original)). Further, Defendants assert that the methods of manufacture disclosed in the '355 Patent's specification all result in mixtures of the α and β polymorphs only, and all of the examples include only the α and

[4] Nevertheless, Defendants argue that this portion of the specification, which provides that "[i]t is possible that a certain amount of the relatively amorphous rifaximin γ can also be present," is a single passage that is at odds with the remainder of the specification. (Def. Open. Br. at 18). The Court disagrees. As already described, other portions of the specification contemplate the presence of rifaximin polymorphs in addition to α and β. (*See, e.g.*, '355 Patent at 8:27–30, 1:55–57, 2:24–38, 2:44–45 & 1:23–26).

β polymorphs. (Def. Open. Br. at 13; Def. Resp. Br. at 3). Finally, Defendants point out that "[t]he specification goes on to describe the various permitted percentages of the β form of rifaximin with '***the*** remaining percentage being the α polymorph,'" not any other polymorph. (Def. Open. Br. at 13 (citing '355 Patent at 5:13–35) (emphasis added)). The Court is not convinced that these passages are sufficient to import a limitation into the entire claim.

"When consulting the specification to clarify the meaning of claim terms, courts must not import limitations into the claims from the specification . . . unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exc[lus]ion or restriction." *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1352 (Fed. Cir. 2010) (internal quotation marks and citations omitted). The passages cited by Defendants do not evince such manifest exclusions, particularly when considered in light of the claim language which uses "open" terms such as "comprising," "containing," and "mixture" and the specification which makes express references to other rifaximin polymorphs. (*See, e.g.*, '355 Patent at 12:62–65, 7:61–8:1, 8:26–30, 1:55–57, 2:24–38, 2:44–45 & 1:23–26). In fact, as the Federal Circuit has cautioned, it would be inappropriate for the Court to limit Claim 1 to the specific preferred embodiments cited by Defendants, where, as here, other intrinsic evidence including the claim language and other portions of the specification, indicate that the claim term is not so limited. *Laryngeal Mask Co. v. Ambu A/S*, 618 F.3d 1367, 1372 (Fed. Cir. 2010). As such, Defendants' proposed Initial Construction would impermissibly import limitations from the specification into the claims. *See Continental Circuits LLC v. Intel Corp.*, 915 F.3d 788, 797 (Fed. Cir. 2019) ("[D]isclosing only the ProbelecXB 7081 embodiment, without more, does not result in a clear disavowal of claim scope."); *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1309 (Fed. Cir. 2007) (rejecting appellant's attempt to import a limitation from the specification into the claim because

the specification made reference to the limitation only "on occasion" and because the appellant failed "to identify language that would require" the proposed limitation "in every case").

Third, Defendants argue that the patentee disclaimed rifaximin compositions containing rifaximin polymorphs other than α and β during prosecution. (Def. Open. Br. at 13–16; Def. Resp. Br. at 5–8). For the reasons set forth below, the Court disagrees. Generally speaking, courts indulge a "heavy presumption that claim terms carry their full ordinary and customary meaning, unless the patentee unequivocally imparted a novel meaning to those terms or expressly relinquished claim scope during prosecution." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003) (internal quotation marks and citations omitted). When the patentee makes clear and unmistakable prosecution arguments limiting the meaning of a claim term in order to overcome a rejection, the courts limit the relevant claim term to exclude the disclaimed matter. *Id.* at 1323–24. "When the prosecution history is used solely to support a conclusion of patentee disclaimer, the standard for justifying the conclusion is a high one." *Avid Tech., Inc. v. Harmonic, Inc.*, 812 F.3d 1040, 1045 (Fed. Cir. 2016). "[T]he standard for disavowal is exacting, requiring clear and unequivocal evidence that the claimed invention includes or does not include a particular feature." *Poly-America, L.P. v. API Indus., Inc.*, 839 F.3d 1131, 1136 (Fed. Cir. 2016). The Federal Circuit has emphasized that it will not limit a claim term's ordinary meaning based on an ambiguous disclaimer since an ambiguous disclaimer does not advance the patent's notice function or justify public reliance. *SanDisk Corp. v. Memorex Prod., Inc.*, 415 F.3d 1278, 1287 (Fed. Cir. 2005). There is no "clear and unmistakable" disclaimer if a prosecution argument is subject to more than one reasonable interpretation, one of which is consistent with a proffered meaning of the disputed term. *See Golight, Inc. v. Wal–Mart Stores, Inc.*, 355 F.3d 1327, 1332 (Fed. Cir. 2004). The question here, therefore, is whether any of the applicant's prosecution arguments to

the examiner have no reasonable interpretation other than to disavow rifaximin compositions containing rifaximin polymorphs other than just α and β.

Defendants first direct the Court's attention to the prosecution history of the '355 Patent itself. During prosecution of the '355 Patent, the patent examiner rejected the then pending Claim 1 as obvious over the '644 Patent to Viscomi, which disclosed pharmaceutical compositions comprising polymorphic forms α, β, and γ of rifaximin. (D.E. No. 79-6, Ex. 5 ("'355 Patent File History") to Weisbruch Decl. at 5–6).[5] While the examiner noted that Viscomi did not mention specific percentages of the α and β polymorphic forms of rifaximin, the examiner stated that it would have been obvious to one skilled in the art to prepare pharmaceutical compositions comprising different percentages of α and β. (*Id.* at 5). To overcome this rejection, the applicant amended Claim 1 of the '355 Patent from "[a] rifaximin composition comprising mixed crystalline polymorphs rifaximin α and rifaximin β containing about 3–12% (w/w) of the rifaximin β crystalline polymorph in mixture with a remaining percentage of the rifaximin α crystalline polymorph" to add "and from about 2% to about 5% by weight water relative to the weight of the total composition wherein the aqueous dissolution rates of the α and β forms provide a fast acting portion and a slow acting portion of rifaximin antibiotic." (*Id.* at 10). In making this amendment, the applicant argued that

> he believes he has developed a certain combination of rifaximin polymorphs that provides gastrointestinal antibiotic activity against bacteria residing in the upper and lower GI tract so that normal GI bacteria do not exhibit overgrowth and are maintained in a balanced check. Applicant believes that the ratio of α to β polymorph recited by his claims provides an appropriate mix of fast and slow dissolving rifaximin polymorphs to perfect this balanced check of overgrowth.

[5] Unless otherwise noted, pin cites to Docket Entry Number 79-6 refer to the pagination automatically generated by the Court's electronic filing system.

(*Id.* at 13). The applicant noted that, in contrast to the present invention, "Viscomi does not provide any ratio of α and β polymorphs nor any disclosure about use of a slow dissolving polymorph to prevent overgrowth of normal GI flora." (*Id.* at 14). Further, when distinguishing Viscomi, the applicant explained that "Viscomi discloses that the α polymorph rapidly dissolves and the γ polymorph dissolves at a moderately fast rate while the β form hardly dissolves at all." (*Id.*). Because one would want a fast acting remedy to treat a GI infection such as traveler's diarrhea, the applicant noted that Viscomi's disclosures would lead the skilled practitioner to either choose the α polymorph or a combination of α and γ polymorphs for a combination of fast acting and moderately fast acting rifaximin polymorphs, but not the α and slow acting β polymorph as claimed. (*Id.*). Accordingly, the applicant argued that the obviousness rejection over Viscomi should be withdrawn. (*Id.* at 13–15). The patent issued shortly thereafter. (*Id.* at 16–22).

Defendants argue that "[i]n making these statements, the [a]pplicant confirmed that the claimed invention of the '355 Patent was limited to rifaximin compositions with specific ratios of α to β." (Def. Open. Br. at 15; *see also* Def. Resp. Br. at 6 & 8). Defendants contend that the "[a]pplicant provided no information or explanation as to how the presence of one or more additional rifaximin polymorphs in the composition might affect the 'fast acting' and 'slow acting' features of the claimed composition or whether the claimed ratios of α and β would be 'an appropriate mix of fast and slow dissolving rifaximin polymorphs to perfect [the] balanced check of overgrowth' if the composition contained other rifaximin polymorphs." (Def. Open. Br. at 15; *see also* Def. Resp. Br. at 8). Defendants further assert that "the Examiner only issued the '355 Patent after the [a]pplicant's amendments and representations regarding that purportedly critical α to β ratio." (Def. Open. Br. at 15). As such, Defendants argue that the applicant disclaimed compositions containing rifaximin polymorphs other than α and β. (*Id.* at 15–16). And even if the

prosecution arguments did not rise to the level of disclaimer or disavowal, Defendants argue that they necessarily inform the construction of "a rifaximin composition." (*Id.* at 16). In response, Plaintiff argues that "[t]he mere fact that the claim was amended to add language that the composition requires additional properties of the already claimed α and β polymorphs" does not mean that other rifaximin polymorphs are necessarily excluded from the scope of Claim 1. (Pl. Resp. Br. at 10–11). Accordingly, Plaintiff argues that Defendants' citations to the prosecution history only state the requirements for the α and β polymorph, but in no way meet the exacting standard of a clear and unmistakable disavowal of additional rifaximin polymorphs. (*Id.*). The Court agrees with Plaintiff.

Here, the applicant did not clearly and unmistakably disclaim rifaximin compositions containing rifaximin polymorphs other than α and β. To be sure, as Defendants point out, the applicant emphasized the importance of the claimed ratio of α and β rifaximin polymorphs as providing an appropriate mix of fast and slow dissolving rifaximin polymorphs to overcome the obviousness rejection. (Def. Open. Br. at 15; Def. Resp. Br. at 8). However, the applicant at no point clearly stated that the rifaximin composition of the invention had to be limited to the rifaximin α and β polymorphs only, and Defendants admit as much. (Def. Resp. Br. at 9). Further, as Plaintiff points out, even though the applicant emphasized the importance of the claimed ratio of α and β, the amended claim still recited the word "comprising" and the applicant also used the open-ended word "mixture" when discussing the claimed composition during prosecution. ('355 Patent File History at 10; *id.* at 14 ("These choices lead away from Applicant's *mixture* of α and β polymorphs at the weight percentages recited by his amended claim 1.") (emphasis added)). These statements undermine any purported disavowal.

Further, the prosecution history here is open to multiple interpretations, at least one of which supports an open-ended construction. More specifically, when distinguishing the claimed invention from Viscomi, the applicant emphasized that "Viscomi does not provide *any* ratio of α and β polymorphs nor *any* disclosure about use of a slow dissolving polymorph to prevent overgrowth of normal GI flora." (*Id.* at 14) (emphasis added). The fact that it was important that the claimed invention *did* provide a specific ratio of α and β polymorphs and *did* disclose the use of a slow dissolving polymorph to prevent overgrowth of normal GI flora, as the applicant argued to overcome the obviousness rejection, does not unequivocally show that the claimed invention could not also include additional rifaximin polymorphs. One interpretation of the prosecution history is that the patentee was merely better defining the rifaximin composition of the invention and adding in some information about why the claimed ratio of α and β was useful because it provided both a fast acting *and* a slow acting portion of rifaximin—and in fact, that is what Claim 1 was amended to recite. (Pl. Resp. Br. at 10–11; *Markman* Hr'g Tr. at 21:8–10). In other words, what was important to the applicant in overcoming the obviousness rejection was that the claimed composition contained a specific ratio of fast and slow dissolving rifaximin polymorphs, not that it necessarily could not include any other rifaximin polymorphs. ('355 Patent File History at 13). And such a reading of the prosecution history is consistent with the claim language and specification of the '355 Patent, which indicate that Claim 1 encompasses more than just the rifaximin α and rifaximin β polymorphs. Further, in distinguishing Viscomi, the applicant noted that Viscomi's disclosures would lead the skilled practitioner to either choose the α polymorph or a combination of α and γ polymorphs for a combination of fast acting and moderately fast acting rifaximin polymorphs, but not the α and slow acting β polymorph as claimed. (*Id.* at 14). However, as Plaintiff points out, one interpretation of this argument is that the applicant was merely

emphasizing that the α and β polymorphs were necessary to the claimed invention, not that they were exclusive. (*Markman* Hr'g Tr. at 52:12–23).

In sum, the statements in the prosecution history relied on by Defendants, while arguably subject to the interpretation Defendants give them, can also be reasonably understood as merely emphasizing the importance of the claimed ratio of α and β rifaximin polymorphs, but not excluding additional unrecited rifaximin polymorphs. *See, e.g., Lucent Techs., Inc. v. Gateway, Inc.*, 525 F.3d 1200, 1211–12 (Fed. Cir. 2008) ("[T]he arguments made by the applicants during prosecution clearly distinguish the claimed method from that of [the prior art], but do not constrain the definition of [the disputed claim term] as urged by the defendants."). Because the statements in the prosecution history are subject to multiple reasonable interpretations, they do not constitute a clear and unmistakable disclaimer of rifaximin compositions containing rifaximin polymorphs other than α and β. *See Cordis Corp. v. Medtronic Ave, Inc.*, 339 F.3d 1352, 1359 (Fed. Cir. 2003) (concluding that a statement made during prosecution "is amenable to multiple reasonable interpretations and it therefore does not constitute a clear and unmistakable surrender").[6]

Defendants next direct the Court's attention to the prosecution history of the '355 Patent's parent, U.S. Patent Number 9,018,225 (the "'225 Patent").[7] During prosecution of the '225 Patent, the patent examiner rejected the then pending claims as obvious over U.S. Publication No.

[6] Defendants' cited case law does not compel a contrary conclusion. To support their prosecution history disclaimer argument, Defendants cite to *E.I. du Pont de Nemours & Co. v. MacDermid Printing Solutions, L.L.C.*, 657 Fed. App'x. 1004, 1016 (Fed. Cir. 2016), where the Federal Circuit found that the district court did not err in construing "dimensionally stable" as requiring a "special annealing process" when the applicants relied solely on that annealing process to overcome prior-art-based anticipation and obviousness rejections and repeatedly characterized the annealing process as "important" and "critical" during prosecution. In contrast, here, as explained above, one reasonable interpretation of the prosecution history is that the applicant was merely emphasizing the importance of the claimed ratio of α and β rifaximin polymorphs, but not excluding additional unrecited rifaximin polymorphs. Further, the applicant at no point stated that it was important and critical that the claimed rifaximin composition contain *only* the α and β rifaximin polymorphs to warrant importing such a limitation into Claim 1.

[7] The Federal Circuit has held that a statement made by the patentee during the prosecution of a patent in the same family as the patent in suit can operate as a disclaimer, particularly where, as here, the later application uses the same claim term. *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1349–50 (Fed. Cir. 2004).

2005/0272754 to Viscomi. (D.E. No. 93-3, Ex. 16 ("'225 Patent File History") to Weisbruch Decl. at 6). To overcome this rejection, the applicant amended the then pending Claim 1 from "the composition comprising mixed crystalline polymorphs rifaximin α and rifaximin β" to add "wherein the composition comprising mixed crystalline polymorphs rifaximin α and rifaximin β contains about 3% up to about 12% (w/w) of the rifaximin β crystalline polymorph in mixture with a remaining percentage of the rifaximin α crystalline polymorph." (*Id.* at 2). In making this amendment, the applicant argued that "Viscomi never discloses or suggests a method for preparing a form comprising a mixture of the α and β forms, wherein the β form amounts to about 3–12% of the total, with 2.5–5% water. Nor does Viscomi disclose or suggest preparation of a mixture of two polymorphs at all." (*Id.* at 7). In addition, to overcome the obviousness rejection, the applicant stated that "Viscomi does not suggest that a mixture of the α form and the β form, wherein the solid contains about 3–12% of the β form, the remainder being the α form, can be obtained." (*Id.* at 8). Accordingly, the applicant argued that the obviousness rejection over Viscomi should be withdrawn, because "[t]he instant claims are amended to recite a composition of a specific mixed polymorphic form, having about 3–12% (claims 1 and 16) of the β form, the balance being the α form, and the composition comprising a defined water content of between 2.5% and 5.0%." (*Id.* at 6 & 9). Defendants argue that in "stating (*inter alia*) that the claimed mixture has 3–12% of the β form with '***the balance being the α form***' and that the prior art Viscomi reference does not disclose or suggest the preparation of '***a mixture of two polymorphs,***' the [a]pplicant made clear that his invention pertained to compositions that include only the two polymorphs α and β and he distinguished his invention from the prior art on that ground." (Def. Resp. Br. at 7). They contend that this is further underscored by the fact that the applicant argued that the specific mixture of α and β would be a "stable, equilibrium composition." (*Id.*). As such, Defendants argue that the

prosecution history of the '355 Patent's parent indicates that the applicant disclaimed compositions that contain other rifaximin polymorphs. (*Id.* at 8). The Court again disagrees.

The applicant did not clearly and unmistakably disclaim rifaximin compositions containing rifaximin polymorphs other than α and β during prosecution of the '355 Patent's parent. In distinguishing the invention of the '225 Patent from Viscomi, the applicant emphasized that Viscomi did not disclose a preparation of a mixture of two polymorphs. ('225 Patent File History at 6 & 8). However, the applicant at no point stated that the scope of the claimed invention was limited to *only* mixtures of two polymorphs, or to mixtures of only the α and β polymorphs, specifically. Rather, one interpretation of these prosecution arguments is that the applicant was merely emphasizing that the α and β polymorphs were necessary to the claimed invention, not that they were exclusive. Accordingly, the Court does not find that these statements amount to a disavowal. *See Gemstar–TV Guide Int'l, Inc. v. Int'l Trade Com'n*, 383 F.3d 1352, 1375 (Fed. Cir. 2004) (rejecting theory of claim disavowal or disclaimer where "[patentee] stated only that the . . . reference was incapable of performing a certain type of search, not that the scope of the claimed invention was limited to that particular type of search"). Further, while the applicant did state during prosecution of the '225 Patent that the claimed composition has 3–12% of the β form with "***the balance"*** or ***"remainder"*** being the α form ('225 Patent File History at 6 & 8), the applicant also used the open-ended words "comprising" and "mixture" when discussing the claimed composition. (*See, e.g., id.* at 6 ("Viscomi never, to the best of [a]pplicant's knowledge, discloses or suggests the preparation of a specific form *comprising* the two polymorphs.") (emphasis added); *id.* at 7 ("Applicant believes this *mixture* to be a stable, equilibrium composition at the stated water content.") (emphasis added)). As such, one reasonable interpretation of the prosecution history is that the applicant was merely emphasizing that Viscomi did not disclose or

suggest the preparation of a mixture of two polymorphs as claimed by the '225 Patent but was not limiting the scope of the invention on that basis. Because the statements in the prosecution history of the '355 Patent's parent are subject to multiple reasonable interpretations, they do not constitute a clear and unmistakable disclaimer of rifaximin compositions containing rifaximin polymorphs other than α and β. *See Cordis Corp.*, 339 F.3d at 1359.[8]

Citing to the Federal Circuit's decision in *Univ. of Mass. v. L'Oreal S.A.*, 36 F.4th 1374, 1379 (Fed. Cir. 2022), Defendants argue that even if the applicant's statements during prosecution of the '355 Patent and '355 Patent's parent do not rise to the level of disclaimer or disavowal, they still necessarily inform the construction of "[a] rifaximin composition." (Def. Open. Br. at 16; Def. Resp. Br. at 11). However, as Plaintiff points out (Pl. Resp. Br. at 11–12), the Federal Circuit's decision in *L'Oreal* is distinguishable because there the Federal Circuit relied on the prosecution history to inform the meaning of a disputed claim phrase, in part, because the meaning of the relevant claim language was ambiguous. *L'Oreal S.A.*, 36 F.4th at 1379 ("Because the meaning of the relevant claim language is not plain, but rather ambiguous for the reasons described in Section II.A, we can look to the prosecution history to 'inform[ ] the meaning of the disputed claim phrase and address[ ] an ambiguity otherwise left unresolved.'"). In contrast, here, as described above, both claim context and the specification unambiguously support an open-ended

[8] Defendants' cited case law does not compel a contrary conclusion. To support their prosecution history disclaimer argument, Defendants cite to *Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1094-95 (Fed. Cir. 2013), which they assert overrides and limits statements in the specification that state that other rifaximin polymorphs may be present. (Def. Resp. Br. at 10). In *Biogen***,** the ordinary meaning of the pharmaceutical claims would have covered *all* antibodies which attack a particular antigen, known as CD20. However, the examiner pointed out the patent did not teach so broad an innovation. In response, rather than challenging the examiner's understanding of the crucial terms, the applicants argued that the specification was enabling for a specific set of anti-CD20 antibodies. *Biogen Idec, Inc.*, 713 F.3d at 1096. "Indeed, the applicants conceded that other 'antibodies directed to the same antigen [i.e., CD20] might have different affinities and functional characteristics,'" and as such limited their claims to antibodies with only a specific set of characteristics. *Id.* Here, by contrast, the examiner at no point explicitly indicated that the claimed rifaximin composition could not encompass rifaximin polymorphs other than α and β. And as explained above, the applicant did not clearly and unmistakably disclaim rifaximin compositions containing rifaximin polymorphs other than α and β during prosecution. As such, Defendants' reliance on *Biogen* is unavailing.

construction of "a rifaximin composition" that encompasses more than just the rifaximin α and rifaximin β polymorphs. Regardless, while prosecution history statements can inform claim construction, the mere fact that the applicant emphasized the importance of the claimed ratio of the α and β rifaximin polymorphs during prosecution does not mean that other polymorphs necessarily must be excluded from the scope of Claim 1, particularly in light of other intrinsic evidence supporting an open-ended construction.

Fourth, Defendants argue that if "[a] rifaximin composition" is not construed as limited to rifaximin mixtures containing only the α and β polymorphs, Claim 1 would be invalid because a POSA would not be informed, with reasonable certainty, whether the claimed percentages refer to a percentage of the amount of just the α and β rifaximin polymorphs or of the total amount of all the rifaximin polymorphs present in the composition, rendering the claim indefinite. (Def. Open. Br. at 16–17; Def. Resp. Br. at 8–9). The Court will not construe "[a] rifaximin composition" to exclude other rifaximin polymorphs as Defendants suggest based on this argument. As the Federal Circuit has emphasized, "[c]laim terms should be given their plain and ordinary meaning to one of skill in the art at the relevant time and cannot be rewritten by the courts to save their validity." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1374 (Fed. Cir. 2014). As such, where the meaning of a claim term is clear based on the sum of the intrinsic evidence, as it is here, the Court will not rewrite the claim to preserve its validity. And while the Court's construction could lead to issues with Claim 1's definiteness, the Court declines to allow this Court's "claim construction to morph into a mini-trial on validity" *id.*, and finds that any indefiniteness challenges can be better addressed at a later time with a more developed record. *See Alcon Research, Ltd. v. Barr Labs. Inc.*, No. 09–0318, 2011 WL 3901878, at *16 (D. Del. Sept. 6, 2011).

iii. The Court is not Convinced by Defendants' Contrary Arguments in Support of Their Alternative Construction

In the alternative, Defendants argue that, to the extent the Court considers a broader construction, they would propose that "[a] rifaximin composition" be construed to mean "[a] composition comprising mixed crystalline polymorphs rifaximin α and rifaximin β, wherein the predominant polymorphs are rifaximin α and rifaximin β, although a certain amount of rifaximin γ (but no other rifaximin polymorphs) may also be present." (Def. Open. Br. at 18–19; Def. Resp. Br. at 11–17). Plaintiff opposes and argues that Defendants' alternative construction, like its initial construction, improperly adds negative limitations into Claim 1. (Pl. Open. Br. at 12; *Markman* Hr'g Tr. at 34:4–21). For the reasons set forth below, the Court agrees with Plaintiff.

First, the Court will begin by addressing the "predominant polymorphs" portion of Defendants' alternative construction. To support the addition of this limitation in Claim 1, Defendants rely on the portion of the specification which provides, "[o]ther rifaximin polymorphs can also be present, but the *predominant polymorphs* are the rifaximin α and rifaximin β polymorphs." ('355 Patent at 7:65–67) (emphasis added). Defendants argue that the "predominant polymorphs" portion of their alternative construction properly gives effect to this passage. (Def. Resp. Br. at 12). However, the claim language, specification, and prosecution history do not support the "predominant polymorphs" portion of Defendants' alternative construction. To start, as already described above, Claim 1 uses "open" claim terms such as "comprising," "containing," and "mixture," which indicate that Claim 1 of the '355 Patent does not exclude additional rifaximin polymorphs. (*See, e.g.*, '355 Patent at 12:62–65). While Claim 1 provides that the claimed rifaximin composition contains 3–12% (w/w) of the rifaximin β polymorph with a remaining percentage of the rifaximin α polymorph, there is nothing in the language of Claim 1 that necessarily suggests that rifaximin α and β must be "predominant." (*Id.* at 12: 62–66). Further,

the specification does not justify importing a "predominant" limitation into Claim 1. While the specification does provide, when describing one of the embodiments of the invention, that "[o]ther rifaximin polymorphs can also be present, but the *predominant* polymorphs are the rifaximin α and rifaximin β polymorphs," this is the only passage in the specification that mentions the word predominant. (*See generally* '355 Patent; *Markman* Hr'g Tr. at 34:18–21). And other portions of the specification, which disclose that other rifaximin polymorphs can be present, do not mention the word "predominant." (*See, e.g.*, '355 Patent at 8:26–30 ("When the water content of the solid reaches the level of between 2.5% and 5.0%, inspection of the X-ray powder diffractogram of the sample can reveal that a mixture of rifaximin α and rifaximin β has been obtained, possibly comprising additional crystalline polymorphs.")). Finally, Defendants have not pointed to any statements made during the prosecution of the '355 Patent that would warrant importing a "predominant" limitation into Claim 1. Accordingly, the Court finds that the "predominant polymorphs" portion of Defendants' alternative construction would improperly import a limitation into Claim 1 based on a single disclosure in the specification. *See Thorner*, 669 F.3d at 1366–67 (limitations from the specification should not be read into claims); *Verizon Servs.*, 503 F.3d at 1309 (rejecting appellant's attempt to import a limitation from the specification into the claim because the specification made reference to the limitation only "on occasion" and because the appellant failed "to identify language that would require" the proposed limitation "in every case"). As such, the Court declines to adopt this portion of Defendants' alternative construction.

Defendants' remaining arguments in support of the "predominant polymorphs" portion of their alternative construction are unavailing. Defendants argue that Plaintiff's own expert, Dr. Jennifer Swift, agreed with this portion of their alternative construction during her deposition. (Def. Resp. Br. at 13–16). Defendants correctly point out that during her deposition, Dr. Swift

repeatedly stated that rifaximin polymorphs α and β would have to be the predominant polymorphs and other polymorphs could only be present in small amounts. (*See, e.g.*, D.E. No. 93-2, Ex. 15 ("Swift Dep.") to Weisbruch Decl. at 117:8–14 & 118:6–14). For example, when asked if her proposed construction of "[a] rifaximin composition" would include any composition comprising rifaximin, Dr. Swift responded by stating, "No, it's not any composition comprising rifaximin. Alpha and beta have to be in a certain ratio, and my expectation is that those are the major two forms. ***Those are the predominant forms.***" (*Id.* at 127:15–21 (emphasis added)). When confronted with the fact that Plaintiff's proposed construction would include "a composition that's 95% gamma and 5% alpha and beta in the appropriate portions," Dr. Swift asked if she could amend her construction of the claim term, saying that if she were to amend it she would adopt the following construction: "Any composition comprising rifaximin where the alpha and beta in this ratio are the predominant forms." (*Id.* at 130:7–23).[9] However, though Dr. Swift's testimony does support the "predominant polymorphs" portion of Defendants' alternative construction, the Court declines to import this limitation into Claim 1 based on Dr. Swift's testimony, which constitutes extrinsic evidence. As already described above, the intrinsic record, including the claim language, the specification, and the prosecution history do not support importing a "predominant" limitation into Claim 1. And the Court will not rely on extrinsic evidence in reaching a contrary conclusion. *See, e.g. Phillips*, 415 F.3d at 1318 ("[A] court should discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history.'" (quoting *Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 716 (Fed. Cir. 1998)).

[9] Though later in her deposition, Dr. Swift stated that she would prefer to stick to the construction as is (Swift Dep. at 133:18–134:14), Dr. Swift's final answer on the topic was the same as her original one. (*Id.* at 145:21–146:1 ("Q. So a person of ordinary skill in the art reading the claims in the context of this patent would understand that the predominant rifaximin polymorphs in the composition are alpha and beta, correct? A. I believe so, yes.").

Finally, in support of the "predominant polymorphs" portion of their alternative construction, Defendants argue that if the Court were to adopt Plaintiff's construction, and not limit Claim 1 to at least require that the predominant polymorphs be α and β as they suggest, Plaintiff's construction would cover "a composition that's 95% gamma and 5% alpha and beta in the appropriate portions" and as such would be too broad. (Def. Resp. Br. at 14 & 16). They point out that even if the composition had only 20% of the γ polymorph, Plaintiff's expert, Dr. Swift testified that she did not know whether the rifaximin composition would have the same critical efficacy that the applicant used to distinguish its invention from the prior art in the prosecution history. (Def. Resp. Br. at 16 (citing Swift Dep. at 131:6–14)). However, it is not clear to the Court that such compositions would even fall into the scope of Claim 1 under Plaintiff's construction. As Plaintiff pointed out, to fall within the scope of the claim, "[a] rifaximin composition" would still need to meet the remaining limitations in Claim 1, including that it be "from about 2% to about 5% by weight water relative to the weight of the total composition." ('355 Patent at 12:66–67; *Markman* Hr'g Tr. at 45:11–46:22 ("[T]he amount of water, is going to govern how much alpha and beta can be there because if you have too much delta or gamma . . . it's going to take you outside of that 2 to 5 weight percent."); *see also* Swift Dep. at 134:15–25). Regardless, as described above, the Court will not adopt the "predominant polymorphs" portion of Defendants' alternative construction where the intrinsic record does not clearly justify importing such a limitation into Claim 1. In addition, adopting the "predominant polymorphs" portion of Defendants' alternative construction would likely create ambiguity and require the Court to further construe the meaning of "predominant." In fact, when asked whether "predominant" would need to be further construed, Defendants could not provide the Court with an answer or a proposal of what "predominant" would mean in the context of the '355 Patent. (*Markman* Hr'g Tr. at 42:14–

43:7).[10] As such, the Court will not introduce such ambiguity into Claim 1, particularly in the absence of any intrinsic evidence that clearly indicates it should do so.

Second, the Court will address the portion of Defendants' alternative construction that provides "a certain amount of rifaximin γ (but no other rifaximin polymorphs) may also be present." (Def. Open. Br. at 9). To support this construction, Defendants again rely on the portion of the specification which provides, "[o]ther rifaximin polymorphs can also be present, but the predominant polymorphs are the rifaximin α and rifaximin β polymorphs. It is possible that a certain amount of the relatively amorphous rifaximin γ can also be present." ('355 Patent at 7:65–8:1). Defendants argue that such a construction is proper because even though it is at odds with the rest of the specification and prosecution history, this passage still only discloses the γ polymorph as potentially being included in the rifaximin composition. (Def. Open. Br. at 18; Def. Resp. Br. at 12). Accordingly, Defendants argue that "to the extent the Court considers a construction of the term '[a] rifaximin composition' that includes additional polymorphs beyond α and β, it can only be construed consistent with the only other teaching of the intrinsic evidence. There would be no written description support for anything further." (Def. Open. Br. at 18–19).

The Court finds that the "γ polymorph" portion of Defendants' alternative construction also improperly imports a negative limitation into Claim 1. To start, as already described above, Claim 1 uses "open" claim terms such as "comprising," "containing," and "mixture," which indicate that Claim 1 of the '355 Patent does not exclude rifaximin polymorphs other than the rifaximin α and rifaximin β polymorphs. (*See, e.g.*, '355 Patent at 12:62–65). And there is nothing in the language

[10] Defendants stated that they do not know whether there is a dispute about what "predominant" means because Plaintiff still has not disclosed to them what polymorphs and in what amounts it contends are in the accused product. (*Markman* Hr'g Tr. at 42:14–19). This concern is, of course, beyond the scope of a *Markman* proceeding. "In claim construction the words of the claims are construed independent of the accused product." *Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343, 1347 (Fed. Cir. 2000). Only after claim construction does the fact finder compare the properly construed claims to the accused device or process. *Catalina Marketing International, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 812 (Fed. Cir. 2002).

of Claim 1 itself to suggest that the only other polymorph that can be included within the scope of the claim is the γ polymorph. Further, the specification does not justify importing such a limitation into the claim. The portion of the specification on which Defendants rely to support their alternative construction provides that "[o]ther rifaximin polymorphs can also be present, but the predominant polymorphs are the rifaximin α and rifaximin β polymorphs. It is possible that a certain amount of the relatively amorphous rifaximin γ can also be present." ('355 Patent at 7:65:8:1). As Plaintiff points out (Pl. Resp. Br. at 10), if the '355 Patent only contemplated that the additional γ polymorph and no other polymorph be present, there would be no reason for the specification to provide that "[o]ther rifaximin polymorphs can also be present," before disclosing that the relatively amorphous rifaximin γ, specifically, may also be present. ('355 Patent at 7:65–8:1). And other portions of the specification, which disclose that other rifaximin polymorphs can be present, do not suggest that the only other polymorph that can be included within the scope of the claim is the γ polymorph. (*See, e.g.,* '355 Patent at 8:26–30. ("When the water content of the solid reaches the level of between 2.5% and 5.0%, inspection of the X-ray powder diffractogram of the sample can reveal that a mixture of rifaximin α and rifaximin β has been obtained, possibly comprising *additional crystalline polymorphs*.") (emphasis added); *see also id.* at 1:23–26 (incorporating by reference [the '196 Patent], which discloses rifaximin polymorphic forms δ and ε.);'196 Patent at 8:37–9:6). Further, Defendants have not pointed to any statements made during the prosecution of the '355 Patent that would suggest that the only other polymorph that can be included within the scope of the claim is the γ polymorph. As such, the Court finds that the "γ polymorph" portion of Defendants' alternative construction would also improperly import a negative limitation into the claims. *Thorner*, 669 F.3d at 1366–67; *Verizon Servs.*, 503 F.3d at 1309.

The Court is not persuaded by Defendants' contention that there would be no written description support for anything other than the γ polymorph. (Def. Open. Br. at 19; Def. Resp. Br. at 12–13). As described above, the Federal Circuit has emphasized that "[c]laim terms should be given their plain and ordinary meaning to one of skill in the art at the relevant time and cannot be rewritten by the courts to save their validity." *Hill-Rom Servs.*, 755 F.3d at 1374. Where the meaning of a claim term is clear based on the sum of the intrinsic evidence, as it is here, the Court will not rewrite the claim to preserve its validity. *Id.* (stating that enablement concerns do not justify departing from plain and ordinary meaning of claim term). And while it is possible that the Court's construction may lead to issues with Claim 1's written description, the Court finds that any such challenges can be better addressed at a later time with a more developed record. *Waters Corp. v. Agilent Techs. Inc.*, No. 18-1450, 2019 WL 6255181, at *4 (D. Del. Nov. 22, 2019).

In sum, after considering claim context, the specification, and the prosecution history and for all the foregoing reasons, the Court adopts Plaintiff's construction and construes "[a] rifaximin composition" to mean "any rifaximin composition."

2. "A pharmaceutical composition" ('355 Patent, Claim 3)

Plaintiff	**Defendants**	**The Court**
Construction of "A pharmaceutical composition" is not necessary. To the extent construction is necessary, "A pharmaceutical composition" is meant to have its plain and ordinary meaning, e.g., "any pharmaceutical composition."	"A pharmaceutical composition comprising mixed crystalline polymorphs rifaximin α and rifaximin β and no other rifaximin polymorphs" ("Defendants' Initial Construction" To the extent a different construction is considered, Defendants would propose: "A pharmaceutical composition comprising mixed crystalline polymorphs rifaximin α and rifaximin β, wherein the predominant rifaximin polymorphs in the pharmaceutical composition are rifaximin α and rifaximin β polymorphs, although a certain amount of rifaximin γ (but no other rifaximin	"Any pharmaceutical composition"

polymorphs) may also be present" ("Defendants' Alternative Construction")

The disputed claim term "[a] pharmaceutical composition" appears in Claim 3 of the '355 Patent, which is dependent on Claim 1 of the '355 Patent and reads as follows:

> 3. A pharmaceutical composition suitable for treatment of gastrointestinal bacterial infections by oral administration comprising an effective amount of a rifaximin composition of claim 1 and a pharmaceutically acceptable carrier.

('355 Patent at 13:6–9). Plaintiff argues that the correct construction of "a pharmaceutical composition" is "any pharmaceutical composition." (Pl. Open. Br. at 16–17). As Plaintiff points out, "[a] pharmaceutical composition" of Claim 3 comprises "a rifaximin composition of claim 1," which, as described above, Plaintiff argues should be construed as "any composition comprising rifaximin." (*Id.* at 17). By using the transitional phrase "comprising," Plaintiff argues that claim 3 does not exclude additional elements in "[a] rifaximin composition" of claim 1, including rifaximin polymorphs in addition to α and β. (*Id.*) And it argues that nothing in the specification or prosecution history further limits the term either. (*Id.*). In contrast, Defendants argue that for the same reasons set forth above with respect to "[a] rifaximin composition" in Claim 1, "[a] pharmaceutical composition" should be construed to mean "[a] pharmaceutical composition comprising mixed crystalline polymorphs rifaximin α and rifaximin β and no other rifaximin polymorphs" or in the alternative "[a] pharmaceutical composition comprising mixed crystalline polymorphs rifaximin α and rifaximin β, wherein the predominant rifaximin polymorphs in the pharmaceutical composition are rifaximin α and rifaximin β polymorphs, although a certain amount of rifaximin γ (but no other rifaximin polymorphs)." (Def. Open. Br. at 19–20). Defendants argue that the term "a rifaximin composition of claim 1" should have the same meaning in Claim 3 as in Claim 1 and there is nothing to indicate that "a pharmaceutically acceptable

carrier" as recited in Claim 3 would include an active ingredient such as rifaximin. (*Id.* at 20). For the reasons set forth below, the Court adopts Plaintiff's construction.

"A pharmaceutical composition" recited in Claim 3 comprises "a rifaximin composition of claim 1." ('355 Patent at 13:6–9). Both parties agree that "a rifaximin composition of claim 1" as recited in Claim 3 should be construed consistently with "[a] rifaximin composition" in Claim 1. (Pl. Open. Br. at 17; Pl. Resp. Br. at 15; Def. Open. Br. at 20; Def. Resp. Br. at 17–18). Thus, the Court's construction of "a pharmaceutical composition" in Claim 3 is dependent on the Court's construction of "a rifaximin composition" in Claim 1, and, accordingly, the parties raise the same arguments regarding the construction of these terms. (Pl. Open. Br. at 16–17; Pl. Resp. Br. at 14–15; Def. Open. Br. at 19–20; Def. Resp. Br. at 17–18). For the same reasons set forth above in Section III(C)(a)(1), the Court finds that the proper construction of "[a] rifaximin composition" in Claim 1 and "a rifaximin composition of claim 1" as recited in Claim 3, mean "any rifaximin composition." As Plaintiff points out, by using the open-ended transitional phrase "comprising," Claim 3 does not further limit this term. (Pl. Open. Br. at 17). And Defendants have not provided the Court with any reason as to why Claim 3 would exclude additional rifaximin polymorphs, were the Court to adopt Plaintiff's construction of Claim 1. (*See* Def. Open. Br. at 19–20; Def. Resp. Br. at 17–18). As such, the Court construes "[a] pharmaceutical composition" to mean "any pharmaceutical composition."

b. Disputed Claim Terms in the '915, '257, and '415 Patents

1. *"A rifaximin polymorphic mixture of α/β form"*
('915 Patent, Claim 1; '257 Patent, Claim 1)

Plaintiff	Defendants	The Court
Construction of "A Rifaximin polymorphic mixture of α/β form" is not necessary. To the extent construction is necessary, "A Rifaximin polymorphic mixture of α/β form" is meant to have its plain and ordinary meaning, e.g., "any Rifaximin polymorphic mixture comprising both the α and β forms of Rifaximin."	"A rifaximin polymorphic mixture of α/β form which contains no other rifaximin polymorphs"	"A rifaximin polymorphic mixture of α/β form which contains no other rifaximin polymorphs"

The disputed claim term "[a] rifaximin polymorphic mixture of α/β form" appears in Claim 1 of the '915 Patent and Claim 1 of the '257 Patent which read as follows:

> ***'915 Patent*** Claim 1. A Rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3, characterized by an X-Ray spectrum with characteristic 2theta values at (relative intensity): 5.32 (11%), 5.78 (19%), 6.50 (27%), 7.24 (45%), 7.82 (61%), 8.80 (100%), 10.50 (59%), 11.02 (35%), 11.58 (32%), 13.08 (20%), 14.42 (26%), 17.32 (48%), 17.68 (93%), 18.58 (79%), 19.52 (61%), 21.04 (52%), 21.60 (30%), and 21.92 (46%).
>
> ***'257 Patent*** Claim 1. A Rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3, characterized by an X-Ray spectrum with characteristic 2theta values at: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92.

('915 Patent at 10:50–57; '257 Patent at 10:66–11:3). Plaintiff argues that the context of the claim language and the intrinsic record support a construction of "[a] rifaximin polymorphic mixture of α/β form" that encompasses "any Rifaximin polymorphic mixture comprising both the α and β forms of Rifaximin" including mixtures with other polymorphic forms of rifaximin in addition to the α and β forms. (Pl. Open. Br. at 18–23). In contrast, Defendants argue that the claim language and intrinsic record support a construction of "[a] rifaximin polymorphic mixture of α/β form,"

which contains no other rifaximin polymorphs. (Def. Open. Br. at 20–24). Accordingly, the parties dispute centers around whether "[a] rifaximin polymorphic mixture of α/β form" encompasses rifaximin polymorphs other than the α and β forms. For the reasons set forth below, the Court adopts Defendants' construction.

ii. The Intrinsic Record Supports Defendants' Construction

In resolving this dispute, the Court will again turn to the words of the claims. *Teleflex, Inc.*, 299 F.3d at 1324. However, claim language is not read in isolation. *Phillips*, 415 F.3d at 1315. Rather, claims are part of a fully integrated written instrument, "consisting principally of a specification that concludes with the claims." *Id.* And "the specification 'is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Id.* As such, claim language must always be read in view of the written description. *Id*. In fact, "[t]he only meaning that matters in claim construction is the meaning in the context of the patent." *Trustees of Columbia Univ. in City of New York v. Symantec Corp.*, 811 F.3d 1359, 1364 (Fed. Cir. 2016) (citing *Phillips*, 415 F.3d at 1316). Thus, it is necessary to review the claim language in light of the specifications to determine if the proper construction of the term "[a] rifaximin polymorphic mixture of α/β form," is one that contains no other rifaximin polymorphs. For the reasons set forth below, the Court finds that though the claim language, standing on its own, leaves open the possibility that the disputed terms may encompass additional rifaximin polymorphs, the claim language, when read in view of the specifications, indicate that the proper construction of "[a] rifaximin polymorphic mixture of α/β form" is one that contains no other rifaximin polymorphs.

Starting first with the words of the claim, though it is close, the Court finds that the claim language leaves open the possibility that "a rifaximin polymorphic mixture of α/β form" may

encompass additional rifaximin polymorphs. On the one hand, as Defendants argue, the language of the Claims defines the claimed rifaximin polymorphic mixture to specifically be of "α/β form," suggesting that the claimed mixture does not include any additional polymorphic forms of rifaximin. (Def. Resp. Br. at 18–19). However, as Plaintiff points out, the disputed claim terms also use the phrase "mixture" before "α/β form," which the Federal Circuit has held does not bar additional, unnamed ingredients. ('915 Patent at 10:50; '257 Patent at 10:66); *Mars, Inc.*, 377 F.3d at 1376. As such, the Claims' use of the term "mixture" suggests that "a rifaximin polymorphic mixture of α/β form" does not necessarily exclude additional rifaximin polymorphs.[11]

While Plaintiff argues that other terms in Claim 1 of the '915 Patent and Claim 1 of the '257 Patent clearly support its open-ended construction, the Court disagrees. More specifically, Plaintiff argues that the use of the word "relative" in Claim 1 of the '915 Patent and Claim 1 of the '257 Patent further compels a construction of "a rifaximin polymorphic mixture of α/β form" that does not exclude additional rifaximin polymorphs. It asserts that "relative" refers to the relation between the α and β rifaximin polymorphs, and the Claims' use of "relative ratio" to describe the percentages of α and β that must be present in the claimed rifaximin polymorphic mixture would be redundant if polymorphic forms of rifaximin other than α and β had been excluded from the claims. (Pl. Open. Br. at 19–20). The Court is not persuaded. As Plaintiff itself contends, the use

[11] Defendants contend that even though the claims use the term mixture, the limiting language that follows the word "mixture," namely that the mixture is "*of α/β form*," indicates that the claim terms do not encompass additional rifaximin polymorphs. (Def. Resp. Br. at 21). Defendants argue that a rifaximin polymorphic mixture that has α, β, and γ is not a rifaximin polymorphic mixture *of α/β form*. (*Id.* at 18). In *Mars*, however, the Federal Circuit rejected a similar argument. *Mars*, 377 F.3d at 1375–76. More specifically, there, in contending that the claim term "mixture of lipid and solid ingredients" did not allow for the presence of additional ingredients, the defendant similarly argued that a mixture that included additional ingredients would not be the same mixture as one consisting of only lipids and solids. *Id.* The Federal Circuit rejected this argument, stating that "[t]his argument misses the point. A mixture with lipids, solids and a third ingredient is a different mixture than one containing *only* lipids and solids, but both are still 'mixture [s] of lipid and solid ingredients' as required by the claims." *Id.* at 1376. Likewise, here, while a mixture that contains only the α and β polymorphs is certainly not the same as a mixture that contains the α, β, and γ polymorphs, both would still be mixtures of α and β as the claim requires. Nevertheless, as explained below, when this claim language is read in view of the specifications and prosecution history, it is clear to the Court that the proper construction of "[a] rifaximin polymorphic mixture of α/β form" is one that contains no other rifaximin polymorphs.

of the word "relative" in the Claims simply appears to refer to the relationship between the α and β rifaximin polymorphs. Its use in the Claims does not necessarily become redundant if the Claims only cover the α and β rifaximin polymorphs because it still serves to describe the relationship between those two polymorphs. (*See, e.g.*, *Markman* Hr'g Tr. at 61:20–21).

Regardless, claim terms must be read in view of the specification, and here, the specifications of the '915 Patent and '257 Patent undercut Plaintiff's argument. As Defendants point out, the specifications use the phrase "relative ratio" even when describing rifaximin mixtures that clearly contain *only* the rifaximin α and β polymorphs. (Def. Resp. Br. at 21–22). More specifically, when describing rifaximin mixtures that were used to create a calibration curve, the specifications of the '915 Patent and '257 Patent provide: "[t]he *relative ratio* between alpha and beta polymorphic forms were determined by DRX (powder) using a calibration curve obtained using two samples of Rifaximin prepared by mixing *pure alpha* (DRX: Enclosure 15) and *pure beta* (DRX: Enclosure 16) forms in a *relative ratio* of 80/20 and 90/10 (these samples were prepared according to EP1557421). The diagnostic diffraction peaks considered in order to quantify the ***relative ratio*** between the alpha and the beta form are the following . . ." ('915 Patent at 7:67-8:8; '257 Patent at 8:9–17) (emphasis added). As these passages explain, the relevant samples at issue used to create the calibration curve were prepared by mixing pure rifaximin α and pure rifaximin β, resulting in a mixture that contains only the rifaximin α and β polymorphs. And the inventors use the word "relative" to describe the relationship between the α and β rifaximin polymorphs in this mixture even though it does not contain any polymorphs other than rifaximin α and β. As such, these portions of the specifications undercut Plaintiff's argument that the Claims' use of the word "relative" compels an open-ended construction of the disputed claim terms.

Plaintiff contends that even though the specifications may use "relative ratio" to describe rifaximin mixtures that only contain the rifaximin α and β polymorphs, the use of the word "relative" is context dependent. (Pl. Resp. Br. at 17). To support this argument, Plaintiff points to the testimony of its expert who stated that it would make sense to use the word "relative" in the context of describing a calibration curve, because "if you're trying to make a calibration curve with two components, you would intentionally only use two components in that mixture." (*Id.* (quoting Swift Dep. at 71:16–24)). However, as recounted above, Plaintiff contends that the Claims' use of the term "relative" would be redundant if polymorphic forms of rifaximin other than α and β had been excluded from the claims. (Pl. Open. Br. at 19). Other than asserting that the use of the word "relative" is context dependent, Plaintiff does not explain why "relative" would not be redundant when used to describe the relationship of rifaximin α and β in a mixture that contains only those two components. As such, the Court finds Plaintiff's argument unavailing.

In sum, when read in view of the specifications, the Claims' use of the word "relative" does not compel an open-ended construction of "a rifaximin polymorphic mixture of α/β form." Nevertheless, on balance, the Claims' use of the term "mixture" suggests that the disputed claim terms do not necessarily exclude unnamed ingredients such as additional rifaximin polymorphs.

"It is axiomatic that the claim construction process entails more than viewing the claim language in isolation." *See Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1305 (Fed. Cir. 2011). As such, this claim language must be read in view of the written description. *Phillips*, 415 F.3d at 1315. And here, the specifications indicate that the proper construction of "[a] rifaximin polymorphic mixture of α/β form" is one that contains no other rifaximin polymorphs. On the one hand, the specifications do use the term "mixture" when referring to the claimed invention, which leaves open the possibility that "a rifaximin polymorphic mixture of α/β

form" may encompass additional unnamed ingredients. (*See, e.g.,* '915 Patent at 3:1–4; '257 Patent at 3: 7–10). However, the remainder of the specifications undercuts any such possibility. To start, in describing the background of the invention, the specifications of the '915 Patent and '257 Patent explain that the conversion between polymorphic forms of rifaximin was a problem in the prior art. More specifically, the specifications explain that the prior art indicates that "polymorphic forms of Rifaximin may easily change their polymorphic form if exposed to different values of relative humidity." ('915 Patent at 2:9–12; '257 Patent at 2:14–17). Further, the specifications explicitly note that "[t]he present inventors found that [] the crystallization and drying conditions" described in the prior art are critical because "they did not consistently afford the *desired α or α/β mixtures* but the *undesired γ polymorphic form or other polymorphic mixtures*." ('915 Patent at 2:18–23 (emphasis added); '257 Patent at 2: 23–28 (emphasis added)). The specifications then go on to explain that the conversion of polymorphic forms from one form to another is "critical" and needs to be taken into account to guarantee the "consistency" of the crystalline form, because of regulatory requirements in the drug industry and because different crystal forms of rifaximin exhibit different pharmaceutical properties. ('915 Patent at 2:9–17 & 33–44; '257 Patent at 2:13–22 & 40–51). In fact, the specifications note that "for the preparation of the drug product the *stability* of the polymorphic forms of Rifaximin (for example film coated tablets) is *critical*." ('915 Patent at 2:45–47 (emphasis added); '257 Patent at 2:52–54 (emphasis added)). Accordingly, because the conversion of one polymorphic form of rifaximin to another was considered critical in guaranteeing the "consistency" of the crystalline form, the specifications state that there was a need to put "appropriate manufacturing procedures in place to consistently yield Rifaximin of the appropriate solid state suitable to minimize changes of the solid state during the preparation of the drug product." ('915 Patent at 2:45–60; '257 Patent at 2:52–67). The

inventors then go on to describe how their invention overcomes these problems in the prior art, stating in the summaries of the inventions that "[i]t has now *surprisingly* been found that a new Rifaximin form, consisting of α/β mixture in a relative ratio of 85/15±3 can be prepared *consistently*[,] solving the problems of the prior art as discussed above." ('915 Patent at 2:64–67 (emphasis added); '257 Patent at 3:3–6 (emphasis added)). The specifications also explain that the inventions have "found a process for the preparation of a *consistent* Rifaximin α/β mixture in a relative ratio of 85/15±3 by crystallization and drying of a new polymorphic form of Rifaximin." ('915 Patent at 3:1–7 (emphasis added); '257 Patent at 3:7–13 (emphasis added)). As such, the specifications state that "it is an object of the present invention" to produce "a Rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3." ('915 Patent at 3:17–19; '257 Patent at 3:24–26).

These passages of the specifications, which explain that the conversion between polymorphic forms of rifaximin was a problem in the prior art, repeatedly emphasize that it is critical to guarantee the consistency of crystalline forms because of regulatory requirements in the drug industry and because different crystal forms of rifaximin exhibit different pharmaceutical properties, disparage prior art processes that did not result in the "*desired α or α/β mixtures*" but rather resulted in "the *undesired γ polymorphic form or other polymorphic mixtures*," and attribute the "surprising[]" properties of the inventions to the fact that an α/β mixture in a relative ratio of 85/15±3 can be prepared *consistently*, indicate that Claim 1 of the '915 Patent and Claim 1 of the '257 Patent do not encompass polymorphs other than the desired and consistently produced α/β forms in a specific ratio. ('915 Patent at 2:9–17, 18–23, 33–44 & 64–67 (emphasis added); '257 Patent at 2:13–22, 23–28, 40–51 & 3:3–6) (emphasis added)). This conclusion is further supported by the fact that the summaries of the inventions state that "[i]t has now *surprisingly* been found

that a new Rifaximin form, *consisting* of α/β mixture in a relative ratio of 85/15±3 can be prepared *consistently*[,] solving the problems of the prior art as discussed above," namely that the consistency and conversion between polymorphic forms of rifaximin was a problem. ('915 Patent at 2:64–67; '257 Patent at 3:3–6) (emphasis added). In addition, the specifications do not disclose a rifaximin mixture that contains polymorphs other than α and β. Rather, each figure and example in the '915 Patent and '257 Patent that depicts or discloses a "[a] rifaximin polymorphic mixture of α/β form," shows mixtures that contain *only* the α and β forms of rifaximin, further indicating that Claim 1 of the '915 Patent and Claim 1 of the '257 Patent do not encompass polymorphs other than the desired and consistently produced α/β forms of rifaximin. (*See, e.g.*, '915 Patent at 8:43–10:47; '257 Patent at 8:52–10:64). As such, though the specifications do use the term "mixture," the Court finds that the use of this term cannot on its own support Plaintiff's open-ended construction.[12] Rather, together, the statements in the specifications recounted above support a construction of "[a] rifaximin polymorphic mixture of α/β form," which contains no other rifaximin polymorphs. *See Retractable Techs., Inc.*, 653 F.3d at 1305.

Plaintiff contends that Defendants' construction improperly adds a negative limitation into Claim 1 of the '915 Patent and Claim 1 of the '257 Patent that can only be supported by a clear and unmistakable disavowal, which is absent here. (Pl. Open. Br. at 20–21; Pl. Resp. Br. at 16–19; *Markman* Hr'g Tr. at 63:19–64:10). The Court disagrees. As the Federal Circuit has held, "a claim term may be clearly redefined without an explicit statement of redefinition" and "[e]ven when guidance is not provided in explicit definitional format, the specification may define claim

[12] Plaintiff also argues that the specifications of the '915 and '257 Patents consistently use the term "relative" when referring to the embodied ratios of α/β, supporting an open-ended construction. (Pl. Open. Br. at 20). However, as explained above, because the specifications of the '915 Patent and '257 Patent use the term "relative" to describe polymorphic mixtures that contain only the α and β polymorphs, the Court does not find this argument persuasive. ('915 Patent at 7:67-8:8; '257 Patent at 8:9-14).

terms by implication such that the meaning may be found in or ascertained by a reading of the patent documents." *Phillips*, 415 F.3d at 1321 (citing *Irdeto Access, Inc.*, 383 F.3d at 1300 and *Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001)). In other words, Federal Circuit case law "does not require explicit redefinition or disavowal" when the written description itself is affirmatively limiting. *Cave Consulting Grp., LLC v. OptumInsight, Inc.*, 725 F. App'x 988, 995 (Fed. Cir. 2018) (citing *Trustees of Columbia Univ. in City of New York*, 811 F.3d at 1363).

Here, the specifications of '915 Patent and '257 Patent are affirmatively limiting. The Federal Circuit's decision in *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296 (Fed. Cir. 2011) is instructive on this point. In *Retractable*, the Federal Circuit construed the term "body" in a claim covering medical syringes to mean a one-piece rather than a multi-piece body even where the claim language left open the possibility that the recited "body" could encompass a syringe body composed of more than one piece. *Retractable Techs.*, 653 F.3d at 1304–05. Relevant to the court's conclusion was that (i) the specifications distinguished prior art syringes for failing to recognize a syringe that could be molded as a one piece body; (ii) the summary of the invention stated that the syringe featured a one piece hollow body; (iii) the specifications, in describing the invention, expressly stated that each syringe embodiment contained a one-piece body; (iv) each figure depicted a syringe body with a one-piece body; and (v) the specifications did not disclose a body that consisted of multiple pieces or indicate that the body is anything other than a one-piece body. *Id.* at 1305. While the Federal Circuit acknowledged that there was a fine line between construing the claims in light of the specification and improperly importing a limitation from the specification into the claims, the court found that a construction of "body" that limited the term to a one-piece body was "required to tether the claims to what the specifications

indicate[d] the inventor actually invented." *Id.* The Court finds the present facts analogous. Like in *Retractable*, here, the specifications of the '915 Patent and '257 Patent (i) underscore that the conversion between polymorphic forms of rifaximin was a problem in the prior art and disparage prior art processes that did not result in the "*desired α or α/β mixtures*" but rather resulted in "the *undesired γ polymorphic form or other polymorphic mixtures*;" (ii) repeatedly emphasize that it is critical to guarantee the consistency of rifaximin crystalline forms and attribute, including in the summaries of the inventions, the "surprising[]" properties of the inventions to the fact that an α/β mixture in a relative ratio of 85/15±3 can be prepared *consistently*; (iii) depict, in each figure and example, "[a] rifaximin polymorphic mixture of α/β form" that contains only the α and β rifaximin polymorphs; and (iv) do not disclose in any figure or example a rifaximin mixture that contains polymorphs other than α and β. ('915 Patent at 2:1–3:19 & 8:43–10:47; '257 Patent at 2:4–3:26 & 8:52–10:64). In other words, while there is a fine line between construing the Claims in light of the specifications and improperly importing limitations from the specifications into the Claims, the Court finds that construing "[a] rifaximin polymorphic mixture of α/β form" to mean "[a] rifaximin polymorphic mixture of α/β form which contains no other rifaximin polymorphs" is "required to tether the claims to what the specifications indicate the inventors actually invented." *Retractable Techs. Inc.*, 653 F.3d at 1305. As such, even though the claim language, which includes the term "mixture," leaves open the possibility that the disputed terms may encompass additional rifaximin polymorphs, the specifications here clearly preclude such a possibility. *Id.*

The prosecution history of the '915 Patent further confirms this understanding.[13] During prosecution of the '915 Patent the applicant again emphasized the importance of the consistency

[13] Here, neither of the parties have cited to the prosecution history of the '257 Patent. Nevertheless, because the '915 Patent is in the same family as the '257 Patent and is its parent, the prosecution history of the '915 Patent is relevant in interpreting the same disputed claim term in the '257 Patent. *Capital Mach. Co. v. Miller Veneers, Inc.*,

of the polymorphic form and criticized prior art methods that "produced the undesired γ polymorphic form or other polymorphic mixtures." (D.E. No. 79-7, Ex. 6 ("'915 Patent File History") to Weisbruch Decl. at 3–4).[14] Further, at multiple points during prosecution, when distinguishing the present invention over U.S. Patent Number 8,067,429 to Gushurst to overcome an obviousness rejection, the applicant of the '915 Patent emphasized that it was the "specific ratio of α/β" claimed by the patent that "produced unexpected stability during physical treatments employed for the dry granulation and tableting." ('915 Patent File History at 5 & 34). The applicant contrasted this to "[o]ther known polymorphs of rifaximin" that "may easily change their polymorphic form if exposed to different values of relative humidity." (*Id.*). Accordingly, the applicants' statements during prosecution, which emphasized the importance of the consistency of the polymorphic form and underscored that it was the specific ratio of α to β claimed by the invention that produced unexpected stability in contrast to other known polymorphs of rifaximin that could easily change their polymorphic form, indicate that the applicant intended to limit the claims to only the consistently produced α/β mixture, which did not contain any other undesired rifaximin polymorphs. In sum, when reading Claim 1 of the '915 Patent and Claim 1 of the '257 Patent in light of the specifications and prosecution history, the Court finds that the correct construction of "[a] rifaximin polymorphic mixture of α/β form" is "[a] rifaximin polymorphic mixture of α/β form which contains no other rifaximin polymorphs."

ii. The Court is not Convinced by Plaintiff's Contrary Arguments

524 Fed. App'x 644, 649 (Fed. Cir. 2013) (stating "that the prosecution history regarding a claim term is pertinent when interpreting the same term in both later-issued and earlier-issued patents in the same family").

[14] Unless otherwise noted, pin cites to Docket Entry Number 79-7 refer to the pagination automatically generated by the Court's electronic filing system.

Plaintiff's remaining arguments to the contrary are unavailing. *First*, citing to the Federal Circuit's decision in *Cont'l Cirs. LLC v. Intel Corp.*, 915 F.3d 788, 798 (Fed. Cir. 2019), Plaintiff argues that merely comparing and contrasting the present invention to that of the prior art is not sufficient to limit the claims as Defendants request. (Pl. Resp. Br. at 18). The Court finds *Cont'l Cirs. LLC* distinguishable. In *Cont'l Cirs. LLC* the Federal Circuit reviewed the construction of claim terms in patents directed to a "multilayer electrical device," which included claim limitations regarding the "surface," "removal," or "etching" of "a dielectric material." *Cont'l Cirs. LLC*, 915 F.3d at 792–93. The district court construed the relevant terms to require that the "surface," "removal," or "etching" of the dielectric material be "produced by a repeated desmear process," in part because the specification "repeatedly distinguishe[d] the process covered by the patent from the prior art and its use of a 'single desmear process.'" *Id.* at 794. In finding that the district court erred in limiting the claims to require a repeated desmear process, the Federal Circuit noted that merely comparing and contrasting the present technique to that of the prior art, by describing the double desmear process as "contrary to" or "in stark contrast" to the "single desmear process" of the prior art, was not sufficient to rise to the level of a clear and unmistakable disavowal that could limit the construction of the disputed claim term. *Cont'l Cirs. LLC*, 915 F.3d at 797–98. However, as explained above, although "[i]n general, statements about the difficulties and failures in the prior art, *without more*, do not act to disclaim claim scope," *Retractable Techs.*, 653 F.3d at 1306 (emphasis added), Federal Circuit case law does not require explicit redefinition or disavowal" when *the description itself* is affirmatively limiting. *Cave Consulting Grp., LLC*, 725 F. App'x at 995. And here, as described above, the descriptions of the inventions in the '915 Patent and '257 Patent are affirmatively limiting. More specifically, the specifications do more than just compare and contrast the "rifaximin polymorphic mixture of α/β form" as "contrary to" or in "stark contrast

to" the prior art. Instead, the specifications explicitly characterize the α or α/β mixtures as *desired* and disparage the γ polymorphic form or other polymorphic mixtures, produced in the prior art as *undesired.* ('915 Patent at 2:18–23; '257 Patent at 2:23–28). And they further underscore that the conversion between polymorphic forms of rifaximin was a problem in the prior art, emphasize that it is critical to guarantee the consistency of crystalline forms, and attribute the "surprising[]" properties of the invention to the fact that an α/β mixture in a relative ratio of 85/15±3 can be prepared consistently. ('915 Patent at 2:9–67; '257 Patent at 2:13–3:6). As such, unlike *Cont'l Cirs. LLC*, the specifications here do more than discuss certain disadvantages of the prior art methods and are rather affirmatively limiting. *Cave Consulting Grp., LLC*, 725 F. App'x at 995; (*Markman* Hr'g Tr. at 62:21–63:15).

The Federal Circuit's decision in *Cave Consulting Grp., LLC v. OptumInsight, Inc.*, 725 F. App'x 988 (Fed. Cir. 2018) is instructive in addressing Plaintiff's argument. In *Cave Consulting Grp., LLC*, the Federal Circuit reviewed the construction of claim terms in a patent directed to a "a method for measuring physician efficiency and patient health risk stratification," which included claim limitations for calculating "weighted episode of care statistics" to determine the physician's efficiency score. *Cave Consulting Grp., LLC*, 725 F. App'x at 989–90. The district court construed "weighted episode of care statistics" such that it included both indirect and direct standardization. *Id.* at 990. In finding that the district court erred in construing the claims to include direct standardization, the Federal Circuit relied on the specification which consistently stated that the calculation of "weighted episode of care statistics" according to its method used indirect standardization and distinguished its method that used indirect standardization from the purportedly error-generating prior art methods that used direct standardization. *Id.* at 994. The court held that disclaimer through "clear and unmistakable" disavowal, in that case, was not

necessary where the description itself was affirmatively limiting. *Id.* at 995. Further, though the court acknowledged that in general, statements about the difficulties and failures in the prior art, without more, do not limit claim terms, the court noted that in that case, the specification at issue did "more than discuss certain disadvantages of the prior art methods. It distinguishe[d] its invention from them, particularly pointing out what the invention d[id] not use." *Id.* at 995. Here too, the specifications of the '915 Patent and '257 Patent do more than discuss certain disadvantages of the prior art methods. Instead, they specifically distinguish the present inventions which include an α/β mixture in a relative ratio of 85/15±3 that can be prepared *consistently*, from prior art methods that did not result in the "*desired α or α/β mixtures*" but rather resulted in "the *undesired γ polymorphic form or other polymorphic mixtures*." ('915 Patent at 2:18–23 & 64–67 & '257 Patent at 2:23–28 & 3:3–6). As such, like in *Cave Consulting Grp., LLC*, the specifications in the '915 Patent and '257 Patent are affirmatively limiting and indicate that the claims do not encompass polymorphs other than the desired and consistently produced α/β polymorphs. *See also In re Abbott Diabetes Care Inc.*, 696 F.3d 1142, 1148–49 (Fed. Cir. 2012) (concluding that term "electrochemical sensor" did not include "external cables and wires connecting the sensor to its control unit," despite there having been no explicit disclaimer of cables or wires because the specification defined the term by implication and "contain[ed] only disparaging remarks with respect to the external cables and wires of the prior-art sensors" and a construction including them would be inconsistent with the stated benefits of the invention).

Second, Plaintiff argues that the fact that the '915 and '257 Patent specifications highlight the need to consistently create a stable rifaximin mixture of α/β form in a relative ratio of 85/15±3 does not necessarily mean that no other rifaximin polymorphs can be present. (Pl. Resp. Br. at 17–18). Plaintiff points to the testimony of its expert who stated that "you can make a stable

alpha/beta composition . . . in a variety of mixtures," suggesting that the claimed α/β could be stable even in the presence of additional rifaximin polymorphs. (*Id.* at 18 (citing Swift Dep. at 170:18–20)). Such an interpretation, however, is not supported by either the specifications or the prosecution history. Here, the specifications of the '915 Patent and '257 Patent explicitly disparage prior art processes that did not result in the "*desired α or α/β mixtures*" but rather resulted in "the *undesired γ polymorphic form or other polymorphic mixtures*," indicating that the claimed α/β composition would not meet the objectives of the invention if it existed in a mixture with undesired polymorphs. ('915 Patent at 2:9–44; '257 Patent at 2:13–51). Further, during prosecution, the applicant for the '915 Patent emphasized that it was the "specific ratio of α/β" claimed by the patent that "produced unexpected stability during physical treatments employed for the dry granulation and tableting." ('915 Patent File History at 5 & 34). The applicant contrasted this to "[o]ther known polymorphs of rifaximin" that "may easily change their polymorphic form if exposed to different values of relative humidity," indicating that the claimed α/β mixture could not be stable in a mixture with such other polymorphs of rifaximin that could easily change their polymorphic form, but only in the specific α/β mixture claimed. (*Id.*). As such, the Court finds Plaintiff's argument and its reliance on its expert unavailing.

Similarly unavailing is Plaintiff's expert's opinion that the specifications' statements, which disparage prior art processes that result in "the undesired γ polymorphic form or other polymorphic mixtures," do not exclude additional rifaximin polymorphs from the scope of the claims. When asked whether the '915 Patent and '257 Patent are teaching that use of the claimed 85/15 ±3 α/β mixture allegedly avoids the problems of the prior art of having other undesired rifaximin polymorphs in the compositions, Dr. Swift responded by stating, "[s]ome of it's a matter of scale here. If all of your material winds up being an undesirable form, then that's a problem.

Here this patent is not talking about making all of something else." (Swift. Dep. at 165:2–13). Again, there is no basis in the specifications or prosecution history for such an interpretation. The specifications unequivocally disparage prior art methods for producing the "*undesired γ polymorphic form or other polymorphic mixtures*." ('915 Patent at 2:18–23; '257 Patent at 2: 23–28). They at no point disparage prior art methods for *mostly* producing such undesired polymorphs, or suggest that the scope of the invention would exhibit the same consistency were it to include *small amounts* of undesired rifaximin polymorphs. As such, though Plaintiff contends that Dr. Swift's testimony supports a construction of "[a] Rifaximin polymorphic mixture of α/β form," which does not exclude additional rifaximin polymorphs, the Court will not rely on extrinsic evidence in adopting a construction that is belied by the intrinsic evidence. *See, e.g. Phillips*, 415 F.3d at 1318 ("[A] court should discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history.'" (quoting *Key Pharms.*, 161 F.3d at 716)).

Third, Plaintiff argues that Defendants' construction is undercut by the fact that the specifications do disclose other rifaximin polymorphs. (Pl. Open. Br. at 20 (citing '915 Patent at 1:58–65); '257 Patent at 1:61–2:3). More specifically, in the background of the invention, the specifications of the '915 Patent and '257 Patent state the following:

> Literature data confirm that [rifaximin] may be isolated in different crystalline forms identified with the letters of the Greek alphabet: the α, β and γ forms were disclosed on 2004 (EP1557421 by Alfa Wasserman), the ε and δ forms on 2006 (EP1698630 by Alfa Wasserman), the ζ, η, a dry, ι forms on 2009 (WO2009108730 by Salix Pharmaceuticals, Ltd.), κ and θ forms on 2011 (WO2011153444 by Salix Pharmaceuticals, Ltd.). Moreover[,] it is known that Rifaximin may exist in an amorphous form (WO2008035109 by Cipla Limited) and in an amorphous halo form (WO2011080691).

('915 Patent at 1:58–65; '257 Patent at 1:61–2:3). Nevertheless, though the specifications may in fact describe other polymorphic forms of rifaximin that have been disclosed in the prior art, they then both go on to explicitly disparage prior art processes that resulted in "the *undesired γ polymorphic form or other polymorphic mixtures*." ('915 Patent at 2:18–23; '257 Patent at 2: 23–28). As such, Plaintiff's reliance on these background passages of the specifications to support a construction of "[a] rifaximin polymorphic mixture of α/β form" that includes other rifaximin polymorphs is unavailing in light of the remainder of the intrinsic record, which indicates that other rifaximin polymorphs are not encompassed by the presently claimed inventions.

Fourth, Plaintiff points out that there are prior art patents cited on the face of the '915 Patent and '257 Patent that have claims with explicit exclusionary language. For example, Plaintiff points to Claims 1 and 4 of U.S. Patent No. 7,902,206 (the "'206 Patent"), which claim a "Rifaximin in polymorphic form α [β in claim 4] *free from* other polymorphic forms of rifaximin not derived from Form α [β in Claim 4]."). (Pl. Open. Br. at 21 (quoting D.E. No. 80-2, Ex. 1 ("'206 Patent") to D.E. No. 80-1 ("Abraham Decl.") at 9:47–51 & 56–60); *see also* D.E. No. 80-18, Ex. N., U.S. Patent Number 8,193,196 ("'196 Patent") to Swift Decl. at 10:26–30 & 47–51 (claiming "Rifaximin in polymorphic form δ [ε in claim 23] *free from* other polymorphic forms of rifaximin not derived from form δ [ε in claim 23] . . ") (emphasis added))). Plaintiff argues that based on these prior art patents, which were cited on the face of the '915 Patent and '257 Patent, the inventors were aware of how to exclude other rifaximin polymorphs with explicit exclusionary language. And because the claims at issue do not include such explicit language, Plaintiff contends that they should not be construed to exclude additional unrecited rifaximin polymorphs. The Court is not persuaded. While the prior art patents to which Plaintiff points may demonstrate one way in which a patentee may exclude other rifaximin polymorphs from the scope of his or her claims,

it by no means constitutes the exclusive way to do so. And here when reading the claims in light of the specification and prosecution history, the Court finds that the correct construction of "[a] rifaximin polymorphic mixture of α/β form" is "[a] rifaximin polymorphic mixture of α/β form which contains no other rifaximin polymorphs."

In sum, after considering claim context, the specifications, and the prosecution history and for all the foregoing reasons, the Court adopts Defendants' construction and construes "[a] rifaximin polymorphic mixture of α/β form" to mean "[a] rifaximin polymorphic mixture of α/β form which contains no other rifaximin polymorphs."

2. "A pharmaceutical composition"
('915 Patent, Claim 2; '257 Patent, Claim 2)

Plaintiff	**Defendants**	**The Court**
Construction of "A pharmaceutical composition" is not necessary. To the extent construction is necessary, "A pharmaceutical composition" is meant to have its plain and ordinary meaning, e.g., "any pharmaceutical composition."	"A pharmaceutical composition comprising a rifaximin polymorphic mixture of α/β form and no other rifaximin polymorphs"	"A pharmaceutical composition comprising a rifaximin polymorphic mixture of α/β form and no other rifaximin polymorphs"

The disputed claim term "[a] pharmaceutical composition" appears in Claim 2 of the '915 Patent and Claim 2 of the '257 Patent, which are dependent on Claim 1 of the '915 Patent and Claim 1 of the '257 Patent, respectively and both read as follows:

> 2. A pharmaceutical composition comprising the polymorphic mixture of Rifaximin of claim 1**,** and a vehicle, excipient, or formulative ingredient.

('915 Patent at 10:58–60; '257 Patent at 11:4–6). Plaintiff argues that the correct construction of "a pharmaceutical composition" is "any pharmaceutical composition." (Pl. Open. Br. at 23–24). As Plaintiff points out, "[a] pharmaceutical composition" of Claim 2 of the '915 Patent and Claim 2 of the '257 Patent comprise "the polymorphic mixture of Rifaximin" of Claim 1 of the '915

Patent and Claim 1 of the '257 Patent. And, as described above, Plaintiff argues that "[a] Rifaximin polymorphic mixture of α/β form" in Claim 1 of the '915 Patent and Claim 1 of the '257 Patent should be construed as "any Rifaximin polymorphic mixture comprising both the α and β forms of Rifaximin." (*Id.* at 24). By using the terms "comprising" and "mixture," Plaintiff argues that Claim 2 of the '915 Patent and Claim 2 of the '257 Patent do not exclude additional elements from the polymorphic mixture of Rifaximin of Claim 1 of the '915 Patent and Claim 1 of the '257 Patent. (*Id.*) And it argues that nothing in the specifications or prosecution history further limit the term either. (*Id.*). In contrast, Defendants argue that "[a] pharmaceutical composition" should be construed as "[a] pharmaceutical composition comprising a rifaximin polymorphic mixture of α/β form and no other rifaximin polymorphs." (Def. Open. Br. at 25). Defendants argue that the term "the polymorphic mixture of Rifaximin of claim 1" should have the same meaning in Claim 2 of the '915 Patent and Claim 2 of the '257 Patent as "[a] Rifaximin polymorphic mixture of α/β form" in Claim 1 of '915 Patent and Claim 1 of the '257 Patent and there is nothing to indicate that "a vehicle, excipient, or formulative ingredient" as recited in Claim 2 of the '915 Patent and Claim 2 of the '257 Patent would encompass another polymorphic form of rifaximin. (*Id.*). For the reasons set forth below, the Court adopts Defendants' construction.

"A pharmaceutical composition" of Claim 2 of the '915 Patent and Claim 2 of the '257 Patent both comprise "the polymorphic mixture of Rifaximin" of Claim 1 of the '915 Patent and Claim 1 of the '257 Patent. ('915 Patent at 10:58–60; '257 Patent at 11:4–6). Because the Court finds that the proper construction of "[a] Rifaximin polymorphic mixture of α/β form" in Claim 1 of the '915 Patent and Claim 1 '257 Patent is "[a] rifaximin polymorphic mixture of α/β form which contains no other rifaximin polymorphs," "the polymorphic mixture of Rifaximin of claim 1" in Claim 2 of the '915 Patent and Claim 2 of the '257 Patent likewise do not contain additional

rifaximin polymorphs. Further, as Defendants point out, there is nothing to indicate that any other terms recited in Claim 2 of the '915 Patent and Claim 2 of the '257 Patent would encompass another polymorphic form of rifaximin. (Def. Open. Br. at 25). In fact, the specifications of the '915 and '257 Patents provide that "[a]nother object of the present invention is a pharmaceutical composition, in particular a solid formulation, comprising the above polymorphic mixture of Rifaximin as active ingredient." ('915 Patent at 3:23–26; '257 Patent at 3:30–33). Thus, the specifications confirm that the claimed pharmaceutical composition comprises a rifaximin polymorphic mixture of α/β form and no other rifaximin polymorphs. And Plaintiff has not provided the Court with any reason as to why Claim 2 of the '915 Patent and Claim 2 of the '257 Patent would include additional rifaximin polymorphs were the Court to adopt Defendants' construction of Claim 1 of the '915 Patent and Claim 1 of the '257 Patent. (*See* Pl. Open. Br. at 23–24; Pl. Resp. Br. at 20–21). As such, for the reasons set forth in Section III(C)(b)(1), the Court construes "[a] pharmaceutical composition" to mean "[a] pharmaceutical composition comprising a rifaximin polymorphic mixture of α/β form and no other rifaximin polymorphs."

3. *"A tablet, comprising the Rifaximin polymorphic mixture of claim 1"* ('915 Patent, Claim 3; '257 Patent, Claim 10)

Plaintiff	**Defendants**	**The Court**
Construction of "A tablet, comprising the Rifaximin polymorphic mixture of claim 1" is not necessary. To the extent construction is necessary, "A tablet, comprising the Rifaximin polymorphic mixture of claim 1" is meant to have its plain and ordinary meaning, e.g., "any tablet, comprising the Rifaximin polymorphic mixture of claim 1."	"A tablet, comprising the rifaximin polymorphic mixture of α/β form of claim 1 and no other rifaximin polymorphs"	"A tablet, comprising the rifaximin polymorphic mixture of α/β form of claim 1 and no other rifaximin polymorphs"

The disputed claim term "[a] tablet, comprising the Rifaximin polymorphic mixture of claim 1" appears in Claim 3 of the '915 Patent and Claim 10 of the '257 Patent. Both are dependent on Claim 1 of the '915 Patent and Claim 1 of the '257 Patent, respectively, and read as follows:

> A tablet, comprising the Rifaximin polymorphic mixture of claim 1 and a film coating.

('915 Patent at 10:61–62; '257 Patent at 12:11–12). Plaintiff argues that the correct construction of "[a] tablet, comprising the Rifaximin polymorphic mixture of claim 1" is "any tablet, comprising the Rifaximin polymorphic mixture of claim 1." (Pl. Open. Br. at 25–26). As Plaintiff points out, the disputed claim term comprises "the Rifaximin polymorphic mixture" of Claim 1 of the '915 Patent and Claim 1 of the '257 Patent. And, as described above, Plaintiff argues that "[a] Rifaximin polymorphic mixture of α/β form" in Claim 1 of the '915 Patent and Claim 1 of the '257 Patent should be construed as "any Rifaximin polymorphic mixture comprising both the α and β forms of Rifaximin." (*Id.*). By using the term "comprising," Plaintiff argues that Claim 3 of the '915 Patent and Claim 10 of the '257 Patent do not exclude additional elements from the polymorphic mixture of Rifaximin of Claim 1 of the '915 Patent and Claim 1 of the '257 Patent. (*Id.* at 26). And it argues that nothing in the specifications or prosecution history further limit the term either. (*Id.*). In contrast, Defendants argue that "[a] tablet, comprising the Rifaximin polymorphic mixture of claim 1" should be construed as "[a] tablet, comprising the rifaximin polymorphic mixture of α/β form of claim 1 and no other rifaximin polymorphs." (Def. Open. Br. at 26–27). Defendants argue that the intrinsic record of the '915 Patent and '257 Patent make clear that the rifaximin polymorphic mixtures contain only a mixture of α/β form and no other polymorphs and the addition of a tablet limitation does not alter the analysis. (*Id.* at 27). For the reasons set forth below, the Court adopts Defendants' construction.

The disputed claim terms in Claim 3 of the '915 Patent and Claim 10 of the '257 Patent comprise "the polymorphic mixture of Rifaximin of" Claim 1 of the '915 Patent and Claim 1 of the '257 Patent. ('915 Patent at 10:61–62; '257 Patent at 12:11–12). Because the Court finds that the proper construction of "[a] Rifaximin polymorphic mixture of α/β form" in Claim 1 of the '915

Patent and Claim 1 of the '257 Patent is "[a] rifaximin polymorphic mixture of α/β form which contains no other rifaximin polymorphs," "the polymorphic mixture of Rifaximin of claim 1" in Claim 3 of the '915 Patent and Claim 10 of the '257 Patent likewise do not contain any additional rifaximin polymorphs. Further, as Defendants point out, there is nothing to indicate that the addition of a tablet limitation would encompass another polymorphic form of rifaximin. (Def. Open. Br. at 27). And Plaintiff has not provided the Court with any reason as to why Claim 3 of the '915 Patent and Claim 10 of the '257 Patent would include additional rifaximin polymorphs were the Court to adopt Defendants' construction of Claim 1 of the '915 Patent and Claim 1 of the '257 Patent. (*See* Pl. Open. Br. at 25–26; Pl. Resp. Br. at 21–22). As such, for the same reasons set forth above in Section III(C)(b)(1), the Court construes "[a] tablet, comprising the Rifaximin polymorphic mixture of claim 1" to mean "[a] tablet, comprising the rifaximin polymorphic mixture of α/β form of claim 1 and no other rifaximin polymorphs."

4. *"[A] pharmaceutical composition"*
('415 Patent, Claims 1 and 9)

Plaintiff	**Defendants**	**The Court**
Construction of "a pharmaceutical composition" is not necessary. To the extent construction is necessary, "a pharmaceutical composition" is meant to have its plain and ordinary meaning, e.g., "any pharmaceutical composition."	"[A] pharmaceutical composition comprising rifaximin in an α/β polymorphic mixture and no other rifaximin polymorphs"	"[A] pharmaceutical composition comprising rifaximin in an α/β polymorphic mixture and no other rifaximin polymorphs"

The disputed claim term "a pharmaceutical composition" appears in Claims 1 and 9 of the '415 Patent, which read as follows:

> 1. A method of treating a subject suffering from traveler's diarrhea comprising: selecting a subject in need of treatment of traveler's diarrhea; administering to said subject a pharmaceutical composition comprising a therapeutically effective amount of Rifaximin in an α/β polymorphic mixture of 85/15±3 in an amount sufficient to treat the traveler's diarrhea, wherein the Rifaximin α/β polymorphic mixture is characterized by an X-Ray spectrum with

> characteristic 2theta values at: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92.
>
> 9. A method of treating a subject suffering from hepatic encephalopathy comprising: selecting a subject in need of treatment of hepatic encephalopathy; administering to said subject a pharmaceutical composition comprising a therapeutically effective amount of Rifaximin in an α/β polymorphic mixture of 85/15±3 in an amount sufficient to treat the hepatic encephalopathy, wherein the Rifaximin α/β polymorphic mixture is characterized by an X-Ray spectrum with characteristic 2theta values at: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92.

('415 Patent at 10:64–11:9 & 11:29–12:9). Because the '415 Patent specification is substantially the same as the '915 and '257 Patent specifications, Plaintiff argues that "a pharmaceutical composition" appearing in Claims 1 and 9 of the '415 Patent should be construed consistently with "[a] pharmaceutical composition" in Claim 2 of the '915 Patent and Claim 2 of the '257 Patent as "any pharmaceutical composition." (Pl. Open. Br. at 26–27). In contrast, Defendants argue that "a pharmaceutical composition" should be construed as "a pharmaceutical composition comprising rifaximin in an α/β polymorphic mixture and no other rifaximin polymorphs." (Def. Open. Br. at 28). They contend this construction is supported because the rifaximin mixtures of the '415 Patent, like the '915 and '257 Patents, include only the α and β polymorphs and no other polymorphs. (*Id.*). And, Defendants argue, as explained with regards to the similar claim term in Claim 2 of the '915 Patent and Claim 2 of the '257 Patent, "a pharmaceutical composition" cannot be construed to include additional polymorphs of rifaximin beyond those of the claimed rifaximin α/β mixture. (*Id.*). For the reasons set forth below, the Court adopts Defendants' construction.

As the parties point out, the '415 Patent specification is substantially the same as the '915 and '257 Patent specifications. Like the '915 and '257 Patent, the '415 Patent, in describing the background of the invention, explains that the conversion between polymorphic forms of rifaximin

was a problem in the prior art. To start, the specification explains that the prior art indicates that "polymorphic forms of Rifaximin may easily change their polymorphic form if exposed to different values of relative humidity." ('415 Patent at 2:13–21). Further, like the '915 Patent and '257 Patent the specification of the '415 Patent similarly notes that "[t]he present inventors found that [] the crystallization and drying conditions" described in the prior art are critical because "they did not consistently afford the *desired α or α/β mixtures* but the *undesired γ polymorphic form or other polymorphic mixtures*." (*Id.* at 2:22–27) (emphasis added). And it likewise provides that the conversion of polymorphic forms from one form to another is "critical" and needs to be taken into account to guarantee the "consistency" or reproducibility of the crystalline form, which is particularly "important" in view of regulatory requirements in the drug industry and given that different crystal forms of rifaximin exhibit different properties. (*Id.* at 2:3–12 & 39–51). Further, the specification notes that "for the preparation of the drug product the *stability* of the polymorphic forms of Rifaximin (for example film coated tablets) is *critical*." (*Id.* at 2:52–62 (emphasis added)). The specification then describes how the invention overcomes these problems in the prior art by stating that "[i]t has now *surprisingly* been found that a new Rifaximin form, consisting of α/β mixture in a relative ratio of 85/15±3 can be prepared *consistently*[,] solving the problems of the prior art as discussed above." (*Id.* at 3:3–6) (emphasis added).

Because the '415 Patent specification is substantially the same as the '915 and '257 Patent specifications and similarly explains that the conversion between polymorphic forms of rifaximin was a problem in the prior art, repeatedly emphasizes that it is critical to guarantee the consistency of crystalline forms, disparages prior art processes that did not result in the "*desired α or α/β mixtures*" but rather resulted in "the *undesired γ polymorphic form or other polymorphic mixtures*," and attributes the "surprising[]" properties of the inventions to the fact that an α/β

mixture in a relative ratio of 85/15±3 can be prepared *consistently*, the Court agrees with Defendants and finds that, for the same reasons set forth above in Section III(C)(b)(1) and III(C)(b)(2), a "pharmaceutical composition" of Claims 1 and 9 of the '415 Patent, should be construed consistently with a "pharmaceutical composition" of Claim 2 of the '915 Patent and Claim 2 of the '257 Patent to mean "a pharmaceutical composition comprising a rifaximin polymorphic mixture of α/β form and no other rifaximin polymorphs."[15] *Samsung Elecs. Co. v. Elm 3DS Innovations, LLC*, 925 F.3d 1373, 1378 (Fed. Cir. 2019) ("Where multiple patents derive from the same parent application and share many common terms, we must interpret the claims consistently across all asserted patents." (citation omitted)). In fact, the specification of the '415 Patent provides that "[a]nother object of the present invention is a pharmaceutical composition, in particular a solid formulation, comprising the above polymorphic mixture of Rifaximin as active ingredient." ('415 Patent at 3:30–33). Thus, the specification confirms that the claimed pharmaceutical composition comprises a rifaximin polymorphic mixture of α/β form and no other rifaximin polymorphs. Further, there is nothing to indicate that any other terms recited in Claims 1 and 9 of the '415 Patent would encompass another polymorphic form of rifaximin. (Def. Open. Br. at 25). And Plaintiff has not provided the Court with any reason as to why Claims 1 and 9 of the '415 Patent would include additional rifaximin polymorphs were the Court to adopt Defendants' construction of "a pharmaceutical composition" as recited in Claim 2 of the '915 and Claim 2 of the '257 Patent. (*See* Pl. Open. Br. at 26–27; Pl. Resp. Br. at 22–23). As such, for the same reasons set forth above in Section III(C)(b)(1) and III(C)(b)(2), the Court construes "a

[15] The Court also reaches this conclusion based on the prosecution history of the '915 Patent, which is relevant in construing terms in the '415 Patent—a member of the same patent family. *Capital Mach. Co.*, 524 Fed. App'x at 64; *see supra* at 54–55.

pharmaceutical composition" to mean "a pharmaceutical composition comprising a rifaximin polymorphic mixture of α/β form and no other rifaximin polymorphs."

5. *"[T]he pharmaceutical composition comprises 550 mg of Rifaximin α/β polymorphic mixture"*
('415 Patent, Claims 4 and 12)

Plaintiff	Defendants	The Court
Construction of "the pharmaceutical composition comprises 550 mg of Rifaximin α/β polymorphic mixture" is not necessary. To the extent construction is necessary, "the pharmaceutical composition comprises 550 mg of Rifaximin α/β polymorphic mixture" is meant to have its plain and ordinary meaning, e.g., "any pharmaceutical composition comprising 550 mg of a rifaximin composition comprising any polymorphic mixture of rifaximin α/β."	"[T]he pharmaceutical composition comprises 550 mg of Rifaximin α/β polymorphic mixture and no other rifaximin polymorphs"	"[T]he pharmaceutical composition comprises 550 mg of Rifaximin α/β polymorphic mixture and no other rifaximin polymorphs"

The disputed claim term "the pharmaceutical composition comprises 550 mg of Rifaximin α/β polymorphic mixture" appears in Claims 4 and 12 of the '415 Patent, which read as follows:

> 4. The method of claim 1**,** wherein the pharmaceutical composition comprises 550 mg of Rifaximin α/β polymorphic mixture of 85/15±3.
>
> 12. The method of claim 9**,** wherein the pharmaceutical composition comprises 550 mg of Rifaximin α/β polymorphic mixture of 85/15±3.

('415 Patent at 11:14–16 & 12:14–17). Plaintiff argues that the correct construction of "the pharmaceutical composition comprises 550 mg of Rifaximin α/β polymorphic mixture" is "any pharmaceutical composition comprising 550 mg of a rifaximin composition comprising any polymorphic mixture of rifaximin α/β." (Pl. Open. Br. at 27–28). Plaintiff points out that both claims recite the "pharmaceutical composition" of either Claim 1 or Claim 9 of the '415 Patent. (*Id.* at 28). As discussed above, Plaintiff argues that the correct construction of "a pharmaceutical

composition" in Claims 1 and 9 of the '415 Patent is "any pharmaceutical composition." (*Id.*). And by using the term comprising, Plaintiff contends that Claims 4 and 12 do not exclude additional elements from the pharmaceutical composition of Claims 1 and 9. (*Id.*). In contrast, Defendants argue that "the pharmaceutical composition comprises 550 mg of Rifaximin α/β polymorphic mixture" should be construed as "the pharmaceutical composition comprises 550 mg of Rifaximin α/β polymorphic mixture and no other rifaximin polymorphs." (Def. Open. Br. at 28–29). They contend this construction is supported for the same reasons they set forth in support of their constructions of the other pharmaceutical composition claim terms in the '415 Patent,'915 Patent and '257 Patent. Further, Defendants argue that the addition of the "550 mg of Rifaximin α/β polymorphic mixture" limitation does not change the analysis. (*Id.* at 29). For the reasons set forth below, the Court adopts Defendants' construction.

Both Claim 4 and Claim 12 recite the "pharmaceutical composition" of Claim 1 and Claim 9 of the '415 Patent, respectively. As described above, the court finds that the proper construction of "a pharmaceutical composition" in Claims 1 and 9 of the '415 Patent is "a pharmaceutical composition comprising a rifaximin polymorphic mixture of α/β form and no other rifaximin polymorphs." Further, there is nothing to indicate that the addition of the "550 mg of Rifaximin α/β polymorphic mixture" limitation encompasses another polymorphic form of rifaximin. And Plaintiff has not provided the Court with any reason as to why Claims 4 and 12 of the '415 Patent would include additional rifaximin polymorphs were the Court to adopt Defendants' construction of Claims 1 and 9 of the '415 Patent. (*See* Pl. Open. Br. at 27–28; Pl. Resp. Br. at 23–24). As such, for the same reasons set forth above in Section III(C)(b)(1) and III(C)(b)(4), the Court construes the pharmaceutical composition comprises 550 mg of Rifaximin α/β polymorphic

mixture" to mean "the pharmaceutical composition comprises 550 mg of Rifaximin α/β polymorphic mixture and no other rifaximin polymorphs."

6. *"[C]haracteristic 2theta values at (relative intensity): 5.32 (11%), 5.78 (19%), 6.50 (27%), 7.24 (45%), 7.82 (61%), 8.80 (100%), 10.50 (59%), 11.02 (35%), 11.58 (32%), 13.08 (20%), 14.42 (26%), 17.32 (48%), 17.68 (93%), 18.58 (79%), 19.52 (61%), 21.04 (52%), 21.60 (30%), and 21.92 (46%)"* ('915 Patent, Claim 1)

Plaintiff	**Defendants**	**The Court**
"[C]haracteristic 2theta values (relative intensity) at about: 5.32 (11%), 5.78 (19%), 6.50 (27%), 7.24 (45%), 7.82 (61%), 8.80 (100%), 10.50 (59%), 11.02 (35%), 11.58 (32%), 13.08 (20%), 14.42 (26%), 17.32 (48%), 17.68 (93%), 18.58 (79%), 19.52 (61%), 21.04 (52%), 21.60 (30%), and 21.92 (46%)."	Plain and ordinary meaning, i.e., "characteristic 2theta values at (relative intensity): 5.32 (11%), 5.78 (19%), 6.50 (27%), 7.24 (45%), 7.82 (61%), 8.80 (100%), 10.50 (59%), 11.02 (35%), 11.58 (32%), 13.08 (20%), 14.42 (26%), 17.32 (48%), 17.68 (93%), 18.58 (79%), 19.52 (61%), 21.04 (52%), 21.60 (30%), and 21.92 (46%)"	"[C]haracteristic 2theta values (relative intensity) at about: 5.32 (11%), 5.78 (19%), 6.50 (27%), 7.24 (45%), 7.82 (61%), 8.80 (100%), 10.50 (59%), 11.02 (35%), 11.58 (32%), 13.08 (20%), 14.42 (26%), 17.32 (48%), 17.68 (93%), 18.58 (79%), 19.52 (61%), 21.04 (52%), 21.60 (30%), and 21.92 (46%)."

The disputed claim term appears in Claim 1 of the '915 Patent and reads as follows:

> Claim 1. A Rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3, characterized by an X-Ray spectrum with characteristic 2theta values at (relative intensity): 5.32 (11%), 5.78 (19%), 6.50 (27%), 7.24 (45%), 7.82 (61%), 8.80 (100%), 10.50 (59%), 11.02 (35%), 11.58 (32%), 13.08 (20%), 14.42 (26%), 17.32 (48%), 17.68 (93%), 18.58 (79%), 19.52 (61%), 21.04 (52%), 21.60 (30%), and 21.92 (46%).

('915 Patent at 10:50–57). Plaintiff argues that the intrinsic and extrinsic record supports a construction of the disputed claim term that means "characterized by an X-Ray spectrum with characteristic 2theta values (relative intensity) at *about*" the claimed 2theta values and relative intensity values. (Pl. Open. Br. at 30 (emphasis added)). In contrast, Defendants argue that the disputed claim term should be confined to the precise 2theta values and relative intensity values recited in the claim, potentially subject to rounding. (Def. Open. Br. at 33; Def. Resp. Br. at 39).

Accordingly, the parties' dispute centers around whether the recited 2theta values and relative intensity values should be construed as "about" or absolute (subject to rounding). For the reasons set forth below, the Court adopts Plaintiff's construction. Because Plaintiff argues that "about" should modify both the recited 2theta values and relative intensity values, the Court will consider whether the recited 2theta values and relative intensity values should be construed as "about" or absolute in turn.

iii. The Intrinsic Record Supports Construing the Recited 2theta Values as "About"

2theta Values. In resolving this dispute, the Court will turn again to the words of Claim 1. *Teleflex, Inc.*, 299 F.3d at 1324. However, claim language is not read in isolation. *Phillips*, 415 F.3d at 1315. Rather, claims are part of a fully integrated written instrument, "consisting principally of a specification that concludes with the claims." *Id.* And "the specification 'is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Id.* (citation omitted). As such, claim language must always be read in view of the written description. *Id.* Thus, it is necessary to review the claim language in light of the specification to determine if the 2theta values should be construed as "about" or absolute. For the reasons set forth below, the Court finds that though the claim language, standing on its own, does not recite any terms of approximation, the claim language, when read in view of the specification, indicates that the 2theta values should be construed as "about" rather absolute.

To start, as Defendants point out, Claim 1 does not use any words of approximation before reciting the claimed 2theta values. (Def. Open. Br. at 32–33). Nor does it specify an error range that would apply to those values. (Def. Resp. Br. at 31). This is in contrast to other values appearing in the claims of the '915 Patent which do have an accompanying error range. (*See, e.g.*,

'915 Patent at 10:50–51 ("Rifaximin polymorphic mixture of α/β form in a relative ratio of *85/15±3*) (emphasis added); *id.* at 11:6–7 ("to reach a final water content of *6±2%*") (emphasis added)). Defendants also point to claims in the '415 Patent and the '257 Patent, which are in the same patent family, that use an error range or the word "about" with respect to certain values, but not with respect to 2theta values. (*See, e.g.*, '415 Patent at 11:25–28 ("The method of claim 7, wherein the pharmaceutical composition has a hardness of 18.49±1.30 Kp, a thickness of *about* 5.48±0.06mm, a friability of *about* 0.058%, and a disintegration in purified water at 37° C. of *about* 1'20.") (emphasis added); '257 Patent at 12:5–9 & 12:12–19). Accordingly, Defendants argue that when the inventors wanted to specify that recited values were approximate, they deliberately chose to use the word "about" or list an accompanying error range. And because they failed to include such terms of approximation before reciting the claimed 2theta values, Defendants contend that those values should be construed as absolute. (Def. Resp. Br. at 31–32). Because Claim 1 does not use any words of approximation before reciting the claimed 2theta values, claim context alone appears to support Defendants' construction.

Claim language, however, must be read in view of the specification. *Phillips*, 415 F.3d at 1315. And, here, the specification of the '915 Patent indicates that the recited 2theta values should be construed as "about." To start, as Plaintiff points out, the specification of the '915 Patent provides:

> It is understood that all the values and intervals disclosed in the process of the present invention must not be intended as absolute. Any value or interval must be understood by the person of ordinary skill in the art as 'about.' The term 'about', as currently intended, means that any value herein disclosed not necessarily must be exactly taken per se, but that a deviation from this value is within the scope of the present invention, provided that the technical effect herein disclosed is achieved.

('915 Patent at 4:57–65). Based on this passage, Plaintiff argues that the patentees acted as their own lexicographers to make clear to a person of ordinary skill in the art that the claimed 2theta values as recited in Claim 1 should be understood as "about." (Pl. Open. Br. at 30). In response, Defendants argue that this passage only applies to values disclosed in the "***process of the present invention***" and because Claim 1 of the '915 Patent is directed to a ***composition*** of rifaximin, this passage does not apply to the 2theta values recited in Claim 1. (Def. Open. Br. at 37; Def. Resp. Br. at 33). As an initial matter, the cited portion of the specification seems to apply more broadly than Defendants suggest. While the beginning of the recited passage provides that "[i]t is understood that all the values and intervals disclosed in the process of the present invention must not be intended as absolute" it then goes on to state that "[t]he term 'about', as currently intended, means that *any value herein disclosed* not necessarily must be exactly taken per se." ('915 Patent at 4:57–62 (emphasis added); Pl. Resp. Br. at 27). As such, this portion of the specification indicates that the inventors intended that *any value* disclosed in the '915 Patent, including 2theta values, be construed as "about," so long as the technical effect of the invention is still achieved.

` Nevertheless, even if, as Defendants argue, this portion of the specification only applies to values disclosed in the *process of the present invention*, it still supports construing the recited 2theta values in Claim 1 as "about" rather than absolute because the specification indicates that the recited 2theta values were disclosed in the process of the present invention. And as a result, deviations in values that are disclosed in the process of the present invention are *within the scope of the present invention*—not just within the scope of the *process* of the present invention. ('915 Patent at 4:57–65 (emphasis added)). More specifically, after specifying that the values and intervals disclosed in the process of the present invention should not be intended as absolute, the specification goes on to describe a "preferred embodiment" of the process of the present invention

that results in the final rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3. ('915 Patent at 4:66–5:41). As Plaintiff pointed out during the *Markman* hearing, at multiple points during this process, the specification describes intermediate products that are formed before the final rifaximin polymorphic mixture of α/β form. The specification characterizes those intermediate products by X-ray diffraction, indicating that X-ray diffraction is part of the process of the present invention. ('915 Patent at 5:21–5:33; *Markman* Hr'g Tr. at 94:22–95:15). In other words, the specification discloses that part of the process of the present invention is to perform X-ray diffraction on intermediate products, to ensure that ultimately the correct final rifaximin mixture of α/β is formed. Because the 2theta values are obtained as a result of performing X-ray diffraction, the 2theta values are themselves disclosed in the process of the present invention. As such, the specification indicates that the 2theta values should be understood as "about" rather than absolute. ('915 Patent at 5:21–5:33; *Markman* Hr'g Tr. at 94:22–95:15). Further, the final step of the process involves drying and then recovering a "Rifaximin α/β polymorphic mixture 85/15±3" "characterized by an X-Ray spectrum with characteristic 2theta values at (relative intensity): 5.32 (11%), 5.78 (19%), 6.50 (27%), 7.24 (45%), 7.82 (61%), 8.80 (100%), 10.50 (59%), 11.02 (35%), 11.58 (32%), 13.08 (20%), 14.42 (26%), 17.32 (48%), 17.68 (93%), 18.58 (79%), 19.52 (61%), 21.04 (52%), 21.60 (30%), and 21.92 (46%)," as recited by Claim 1 of the '915 Patent. ('915 Patent at 5:34–41). Because the final step of the preferred embodiment of the process of the present invention involves recovering a "Rifaximin α/β polymorphic mixture" with characteristic 2theta values as recited in Claim 1, those values are disclosed in the process of the present invention. Accordingly, the specification indicates that the inventors intended that the 2theta values recited in the patent be construed as "about," because they were disclosed in the process of the present invention. And, while Defendants argue that the values recited in Claim 1 cannot be construed as

about because they are directed to a composition rather than a process, the specification provides, without qualification, that deviations in values that are disclosed in the process of the present invention are *within the scope of the present invention*—not just within the scope of the *process* of the present invention. (*Id.* at 4:57–65 (emphasis added)). As such, this portion of the specification supports construing the recited 2theta values as "about."[16]

Other portions of the specification support construing the recited 2theta values as "about." More specifically, as Plaintiff points out, two Figures disclosed in the specification, namely Figure 4 and Figure 5 that embody the subject matter of the invention, indicate that the 2theta values as recited in Claim 1 should be construed as "about." (Pl. Open. Br. at 31). To start, Figure 4 of the '915 Patent, reproduced below, depicts the X-ray diffraction spectrum of a rifaximin α/β polymorphic mixture in a relative ratio of 87/13. ('915 Patent at 5:34–41 & 9:10–17).

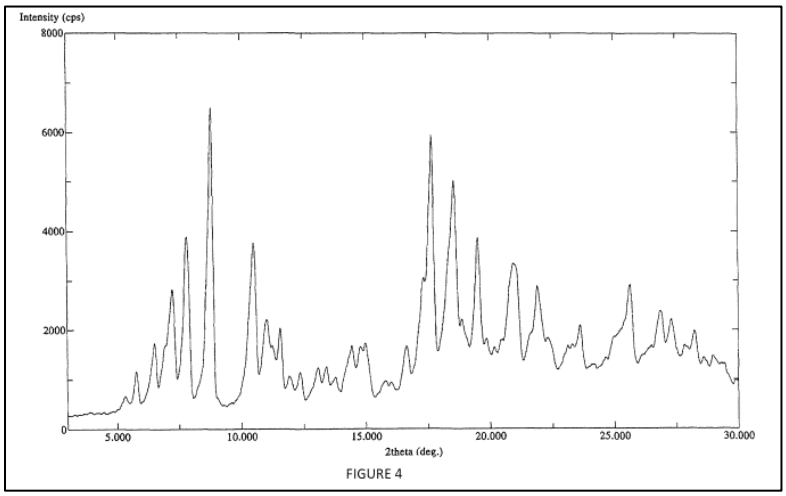

FIGURE 4

[16] As recounted above, Plaintiff argues that the patentees acted as their own lexicographers to make clear to a person of ordinary skill in the art that the claimed 2theta values as recited in Claim 1 are not absolute, but rather, must be understood as "about." (Pl. Open. Br. at 30). The Court need not decide this issue, because regardless, as explained above, the portion of the specification which provides that "all the values and intervals disclosed in the process of the present invention must not be intended as absolute" supports construing the recited 2theta values as "about," rather than absolute, as do other portions of the specification, as explained below. ('915 Patent at 4:57–65); *See Irdeto Access, Inc.*, 383 F.3d at 1300 ("Even when guidance is not provided in explicit definitional format, the specification may define claim terms by implication such that the meaning may be found in or ascertained by a reading of the patent documents." (internal quotation marks and citations omitted))

(*Id.* at Figure 4). The rifaximin composition embodied by Figure 4 is also described in Example 2 of the '915 Patent. (*Id.* at 9:10–17). The 2theta values and relative intensity values that correspond to the rifaximin α/β polymorphic mixture in a relative ratio of 87/13, as disclosed in Figure 4, are the following: 5.32 (11%), 5.78 (19%), 6.50 (27%), 7.24 (45%), 7.82 (61%), 8.80 (100%), 10.50 (59%), 11.02 (35%), 11.58 (32%), 13.08 (20%), 14.42 (26%), 17.32 (48%), 17.68 (93%), 18.58 (79%), 19.52 40 (61%), 21.04 (52%), 21.60 (30%), 21.92 (46%). (*Id.* at 5:37–41 & 9:13–17). Further, as the specification provides, one object of the invention is to provide for "a film coated tablet comprising" a rifaximin α/β polymorphic mixture in a relative ratio of 85/15±3 "together with a process for the preparation of said film coated tablet." (*Id.* at 3:27–29). The specification then goes on to describe the process for the preparation of a film coated tablet. (*Id.* at 6:40–7:12). Figure 5, as reproduced below, depicts the X-ray spectrum of a rifaximin α/β polymorphic mixture in a relative ratio of 85/15±3 that has been formed into uncoated tablets according to that process, after being combined with five different excipients. (*Id.* at 6:65–7:12 & 9:36–10:42).

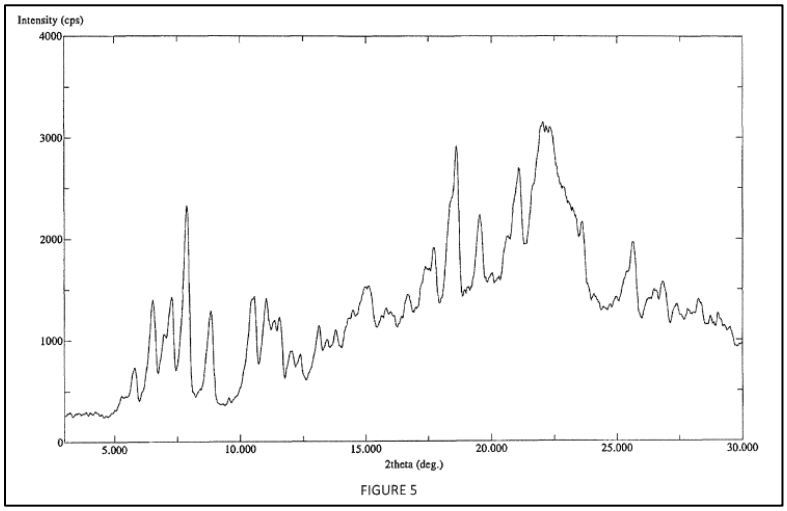

FIGURE 5

(*Id.* at Figure 5). The rifaximin composition embodied by Figure 5 is described in Example 5 of the '915 Patent. (*Id.* at 9:36–10:42). The 2theta values and relative intensity values that

correspond to the rifaximin α/β polymorphic mixture in a relative ratio of 85/15±3, as disclosed in Figure 5, are the following: 5.28 (15%), 5.78 (23%), 6.52 (46%), 7.26 (47%), 7.88 (75%), 8.82 (42%), 10.52 (46%), 11.02 (45%), 11.58 (40%), 13.12 (37%), 14.48 (42%), 17.38 (56%), 17.72 (62%), 18.62 (93%), 19.54 (72%), 21.10 (87%), 21.64 (82%), 22.00 (100%). (*Id.* at 6:67–7:5). The specification also discloses the diagnostic 2theta values and relative intensity values that correspond to the five excipients that have been added to the rifaximin α/β polymorphic mixture of Figure 5, to form uncoated tablets as follows: "[t]he following diagnostic peaks of the employed excipients are also detectable on the DRX spectrum (2theta values, in brackets the relative intensity of the diffraction peaks): 19.10 (50%) and 28.72 (40%) for talc; 22.36 (99%) microcrystalline cellulose; 21.10 (87%) for glycerol palmitostearate; 45.74 (36%) sodium starch glycolate; hydrate silicon dioxide is amorphous and does not present diffraction Peaks. (*Id.* at 7:5–12).

As Plaintiff points out (Pl. Open. Br. at 31–32), though both Figure 4 and Figure 5 embody "[a] rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3," as disclosed by the invention, they each possess characteristic 2theta values that differ. (*Compare* '915 Patent at 6:67–7:5 (reciting 2theta values of 5.28, 5.78, 6.52, 7.26, 7.88, 8.82, 10.52, 11.02, 11.58, 13.12, 14.48, 17.38, 17.72, 18.62, 19.54, 21.10, 21.64, 22.00) *with id.* at 5:37–41 & 9:13–17 (reciting 2theta values of 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, 21.92)).[17] But according to the specification, both Figure 4 and Figure 5

[17] As a note, the intrinsic and extrinsic record indicate that any differences between the 2theta values in Figure 4 and Figure 5 cannot be attributed to any differences in the relative ratio of α/β in the compositions represented by the two Figures. This is because, aside from changes that may occur because of experimental error, the intrinsic and extrinsic record indicate that 2theta values remain consistent as the relative ratio of α/β in the rifaximin mixture changes. This is demonstrated in the specification itself. More specifically, the specification describes a procedure for creating a calibration curve by mixing the α polymorph and β polymorph in known relative ratios of 80/20 and 90/10 and then measuring the resulting 2theta values and peak intensities by X-ray diffraction. ('915 Patent at 7:67–8:15). The specification states that the same 2theta peaks are present at relative ratios of 80/20 and 90/10, indicating that those values remain constant despite any changes in the ratio of α and β. ('915 Patent at 8:9–15). Dr. Swift confirmed this in her deposition. She testified that an 88/12 α/β mixture would have the same 2theta peaks as an 82/18 α/β mixture and suggested that any differences in the 2theta peaks would only be due to experimental error, rather

represent rifaximin mixtures that are preferred embodiments of the present invention prepared according to preferred embodiments of the process of the present invention. (*Id.* at 4:66–5:41 & 6:27–7:12). In fact, as already stated, one object of the invention is to provide for a "a film coated tablet comprising" a rifaximin α/β polymorphic mixture in a relative ratio of 85/15±3 "together with a process for the preparation of said film coated tablet," which is embodied in Figure 5. (*Id.* at 3:27–29). If the Court adopts Defendants' construction and construes the recited 2theta values in Claim 1 as absolute, that construction would exclude from the scope of Claim 1 the rifaximin mixture embodied in Figure 5 that discloses slightly different 2theta values from those disclosed in Claim 1. In so doing, the construction would exclude a preferred embodiment from the scope of the claims of the '915 Patent. (*Id*. at 6:27–7:12). As the Federal Circuit has held, a claim construction that excludes a preferred embodiment is "rarely, if ever, correct." *Vitronics*, 90 F.3d at 1583.[18] Accordingly, because the specification discloses variability in the 2theta values that correspond to "[a] rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3" of the invention, the specification indicates that the 2theta values recited in Claim 1 should be construed as "about." This is consistent with the disclosure of the '915 Patent which, as discussed above, indicates that deviations in 2theta values, which are disclosed in the process of the present

than based on any changes in the ratio of α and β. (Swift Dep. at 87:16–88:4; *see also Markman* Hr'g Tr. at 99:25–100:3). Accordingly, the intrinsic and extrinsic record indicate that any differences between the 2theta values in Figures 4 and 5 cannot be attributed to differences in the relative ratio of α/β.

[18] The fact that Defendants' proposed construction would exclude a preferred embodiment from the scope of the claims in the '915 Patent is further demonstrated by examining Claim 2. Claim 2 of the '915 Patent depends from Claim 1, and is directed to a pharmaceutical composition comprising "the polymorphic mixture of Rifaximin of [C]laim 1, and a vehicle, excipient, or formulative ingredient." ('915 Patent at 10:58-60). Figure 5 of the '915 Patent, which depicts the X-ray spectrum of a rifaximin α/β polymorphic mixture in a relative ratio of 85/15±3 that has been formed into uncoated tablets, after being combined with five different excipients appears to be an embodiment of Claim 2. If "the polymorphic mixture of Rifaximin of [C]laim 1" excludes the rifaximin mixture embodied in Figure 5, such a mixture would also not fall within the scope of Claim 2. As such, Defendants' construction would improperly exclude certain preferred embodiments from the scope of the claims of the '915 Patent.

invention, are within the scope of the present invention. As such, those values "must be understood by the person of ordinary skill in the art as 'about.'" ('915 Patent at 4:57–65).

Defendants contest this interpretation and point out that Figure 4 and Figure 5 are diffractograms of two fundamentally different samples. (Def. Resp. Br. at 33–34 n.5). More specifically, they assert that Figure 5 includes not only a rifaximin α/β polymorphic mixture, but also multiple different excipients, unlike Figure 4 which contains no excipients. (*Id.* (citing '915 Patent at 9:17 & 10:20–36)). Defendants point to the declaration of their expert, Dr. Myerson, who states that based on a visual inspection of the two Figures, it is the excipients that create the different X-ray spectrum depicted in Figure 5, not experimental error associated with measuring the X-ray spectrum of the α/β polymorphic mixture itself. (Def. Resp. Br. at 33–34 n.5; D.E. No. 93-8 ("Second Myerson Decl.") ¶¶ 14–15). As such, Defendants argue that any differences in the X-ray spectrum depicted in Figure 5 as compared to Figure 4 do not change the fact that the 2theta values and relative intensity values for the α/β polymorphic mixture itself—apart from any excipients—should be construed as absolute. (Def. Resp. Br. at 33–34 n.5). Based on the specification, the Court disagrees. When disclosing the 2theta values and relative intensity values that correspond to the rifaximin polymorphic mixture of α/β form as depicted in Figure 5, the specification explicitly accounts for the 2theta values produced by the excipients by listing them out separately from the remaining characteristic 2theta values as follows:

> The uncoated tablets recovered from step c') according to the present invention is characterized by an X-Ray spectrum with characteristic 2theta values at (relative intensity): 5.28 (15%), 5.78 (23%), 6.52 (46%), 7.26 (47%), 7.88 (75%), 8.82 (42%), 10.52 (46%), 11.02 (45%), 11.58 (40%), 13.12 (37%), 14.48 (42%), 17.38 (56%), 17.72 (62%), 18.62 (93%), 19.54 (72%), 21.10 (87%), 21.64 (82%), 22.00 (100%). The following diagnostic peaks ***of the employed excipients are also detectable*** on the DRX spectrum (2theta values, in brackets the relative intensity of the diffraction peaks): 19.10 (50%) and 28.72 (40%) for talc; 22.36 (99%) microcrystalline cellulose; 21.10

> (87%) for glycerol palmitostearate; 45.74 (36%) sodium starch glycolate; hydrate silicon dioxide is amorphous and does not present diffraction peaks.

('915 Patent at 6:65–7:12 (emphasis added); Swift Dep. at 98:20–21). The specification nevertheless still recites *additional* 2theta values corresponding to the α/β polymorphic mixture of Figure 5, separate and apart from the 2theta values recited for the excipients, that differ from the 2theta values reported for the α/β polymorphic mixture corresponding to Figure 4. (*Compare* '915 Patent at 6:67–7:5 *with id.* at 5:34–41 & 9:10–17). As such, the specification, in Figure 4 and Figure 5, discloses variability in the 2theta values that correspond to "[a] rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3" of the invention that cannot be accounted for by the presence of the excipients alone, supporting Plaintiff's construction.

During the *Markman* hearing, Defendants pointed out that the specification only discloses the "diagnostic" peaks that are attributable to the excipients. As a result, because there could be other peaks attributable to the excipients, Defendants argue that it is difficult to determine, from the specification, what peaks correspond with what elements in the composition depicted in Figure 5. (*Markman* Hr'g Tr. at 112:11–113:16). Again, based on the specification, the Court disagrees. In disclosing the diagnostic peaks that are attributable to the excipients in Figure 5, the specification provides, "[t]he following diagnostic peaks *of the employed excipients are also detectable* on the DRX spectrum," indicating that the 2theta values that precede this disclosure are not attributable to the excipients, but to the α/β polymorphic mixture itself. ('915 Patent at 6:65–7:12) (emphasis added). Further, as both parties agree, an X-ray diffraction pattern provides a "fingerprint" for a crystalline form. (Swift Decl. ¶ 57 (citing USP 941); Myerson Decl. ¶ 46). Here, the '915 Patent repeatedly discloses that the "Rifaximin polymorphic mixture of α/β form" of the invention has a "fingerprint" of 18 characteristic 2theta values. ('915 Patent at 5:37–41 &

9:13–17). In fact, for Figure 4, the specification provides that this "fingerprint" corresponds to the following 18 characteristic 2theta values: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, 21.92. (*Id.*). And because Figure 4 depicts the X-ray diffraction spectrum of a rifaximin α/β polymorphic mixture in a relative ratio of 87/13 only, with *no excipients*, the recited 18 characteristic 2theta values must correspond to the fingerprint for the rifaximin α/β polymorphic mixture *only*. (*See Markman* Hr'g Tr. at 114:9–115:21). Similarly, for Figure 5, before disclosing what peaks are attributable to the excipients, the specification also lists out 18 characteristic 2theta values that are nearly identical to the 2theta values disclosed for Figure 4, indicating that those 18 2theta values correspond to the "fingerprint" for the rifaximin polymorphic mixture of α/β form, rather than to any excipients.[19] In other words, when describing Figure 5, the specification first discloses the 18 characteristic 2theta values attributable to the rifaximin polymorphic mixture of α/β form, and then the diagnostic peaks attributable to the excipients. (*Markman* Hr'g Tr. at 114:9–115:21). As such, Defendants' argument is not supported by the specification. And regardless, as discussed, the specification of the '915 Patent still indicates that deviations in 2theta values, which are disclosed in the process of the present invention, are within the scope of the invention. As such, those values must be understood as "about." ('915 Patent at 4:57–65).

ii. The Extrinsic Record is Consistent with the Intrinsic Record and Further Supports Construing the Recited 2theta Values as "About"

"While reference to intrinsic evidence is primary in interpreting claims, the criterion is the meaning of words as they would be understood by persons in the field of the invention." *Verve,*

[19] While Defendants argue that their expert stated that there is no way to determine what peaks correspond with what elements in the composition depicted in Figure 5, the specification here, as described above, shows otherwise. (*Markman* Hr'g Tr. at 111:16–20 & 116:18–117:1). And regardless, the specification of the '915 Patent still indicates that 2theta values must be understood as "about." ('915 Patent at 4:57–65).

LLC v. Crane Cams, Inc., 311 F.3d 1116, 1119 (Fed. Cir. 2002). In fact, in *Verve*, the Federal Circuit emphasized:

> Patent documents are written for persons familiar with the relevant field; the patentee is not required to include in the specification information readily understood by practitioners, lest every patent be required to be written as a comprehensive tutorial and treatise for the generalist, instead of a concise statement for persons in the field.

Id. Here, the extrinsic evidence is consistent with the intrinsic evidence and indicates that at the time of the invention, the 2theta values as recited in Claim 1 would have been understood by a POSA as "about." More specifically, Plaintiff's expert, Dr. Swift, explains that, at the time of the invention, it was recognized that X-ray diffraction and the measurement of 2theta values involved some degree of experimental error. (Swift Decl. ¶¶ 59–60 & 78–79). In support, Dr. Swift points to the United States Pharmacopeia ("USP"), which she characterizes as an authoritative guide on understanding variability in X-ray diffraction readings. (*Id.*). The 2014 edition[20] of the USP states that when using XRPD to compare a known material ("reference") with an unknown material ("specimen"): "[t]he agreement in the 2[theta]-diffraction angles between specimen and reference is within 0.2˚ for the *same crystal form*." (Pl. Open. Br. at 35–36 (citing USP 941 at 507 & Swift Decl. ¶¶ 78–79) (emphasis added)). Based on the USP, Dr. Swift states that a POSA would have understood that the 2theta values as recited in Claim 1 are not absolute and must be understood as "about" to account for experimental error. (Swift Decl. ¶¶ 78–79). Even Defendants' expert, Dr. Myerson, agreed that "there's generally error in X-ray diffraction." (D.E. No. 95-4, Ex. 4 ("Myerson Dep.") to Abraham Decl. at 72:21–73:9). As such, the extrinsic evidence, which is consistent with the intrinsic record in this case, indicates that a POSA would not have required any

[20] According to Plaintiff, the effective filing date of the '915 Patent, at issue here, is March 31, 2014. (Pl. Open. Br. at 8 n.3). As such the 2014 edition of the USP reflects the understanding a POSA would have had at the time of the invention. Defendants do not dispute this.

discussion of the experimental error associated with XRPD diffraction, either in the specification or in the claims, to understand that the recited 2theta values should be construed as "about."

In fact, other courts have declined to construe claims that recite X-ray diffraction values to be exact, even where the claims did not explicitly recite words of approximation before the recited values, based on the fact that it was well understood within the relevant industry that XRPD involves some degree of experimental error. *See Kowa Co., Ltd. v. Amneal Pharms.*, LLC, No. 14-2758, 2017 WL 10667089, at *37–39 (S.D.N.Y. Sept. 19, 2017), *aff'd*, 745 F. App'x 168 (Fed. Cir. 2018) (finding that claim language "characteristic [XRPD] pattern with characteristic peaks" did not require exact match of all peaks because "[a] POSA would understand the plain and ordinary meaning of claims 1 and 24 to include expected experimental error and variation involved with XRPD analysis."); *AstraZeneca AB v. Andrx Labs, LLC*, No. 14-8030, 2017 WL 111928, at *48, (D.N.J. Jan. 11, 2017) ("[T]he Court is mindful that construing the claims to require an exact match is too rigid. The parties and their experts all agree that there will be some range of normal experimental error in an X-ray powder diffractogram."); *Takeda Pharm. Co. v. Handa Pharm., LLC*, No. 11-0840, 2012 WL 1243109, at *12 (N.D. Cal. Apr. 11, 2012) ("[T]he Court concludes that a [POSA] would not have required any discussion of the experimental error associated with XRPD diffraction, either in the specification or in the claims, to understand that the references to 'characteristic peaks at interplanar spacings (d)' allowed for such experimental error."); *Eisai Co. v. Glenmark Pharms., Ltd.*, No. 13-1279, 2015 WL 1228958, at * 8 (D. Del. Mar. 17, 2015) (same); *AstraZeneca AB v. Dr. Reddy's Labs., Inc.*, No. 11-2317, 2013 WL 1847639, at *9 (D.N.J. May 1, 2013) (same); *H. Lundbeck A/S v. Apotex Inc.*, No. 18-0088, 2019 WL 3206016, at *4 (D. Del. July 16, 2019) (same). As in those cases, here the extrinsic evidence, which is consistent with the intrinsic evidence, supports construing the recited 2theta values as "about."

iv. The Court is Not Convinced by Defendants' Contrary Arguments

Defendants' remaining arguments to the contrary are unavailing. *First* Defendants argue that the recited 2theta values in Claim 1 should be construed as absolute because the 2theta values disclosed in the specification are expressed as precise values with two decimal points (e.g., "5.32") and with no words of approximation. (Def. Open. Br. at 34 (citing '915 Patent at 5:34-41, 6:65-7:5, 9:10-17)). In fact, Defendants note that the only place in the specification where 2theta values are modified by the word "about" is with respect to the 2theta values disclosed for a "calibration curve" which the inventors state can be used for determining the relative amounts of the α and β polymorphs in a sample. (*Id.*). However, Defendants point out that the 2theta values disclosed for the calibration curve are expressed only to a single decimal place (e.g., "5.9"), in contrast to the more precise 2theta values for the claimed compositions specified to two decimal places (e.g., "5.32") as recited in Claim 1. (*Id.* (citing '915 Patent at 7:63–8:15)). Defendants contend that this suggests that the inventors specifically chose not to use the word "about" when claiming the 2theta values to a higher degree of precision in Claim 1 and as such those values should be construed as absolute. (*Id.*). In addition, Defendants also point to claims in the '415 Patent and the '257 Patent, which are in the same patent family, that use an error range or the word "about" with respect to certain values, but not with respect to 2theta values. (*See, e.g.*, '415 Patent at 11:25–28 ("The method of claim 7, wherein the pharmaceutical composition has a hardness of 18.49±1.30 Kp, a thickness of *about* 5.48±0.06mm, a friability of *about* 0.058%, and a disintegration in purified water at 37º C. of *about* 1'20.") (emphasis added); '257 Patent at 12:5–9 & 12:12–19)). Accordingly, Defendants argue that when the inventors wanted to specify that recited values were approximate, they deliberately chose to use the word "about" or list an accompanying error range. And because they failed to include such terms of approximation before reciting the claimed 2theta

values, Defendants contend that those values should be construed as absolute. (Def. Resp. Br. at 31). The Court finds Defendants' arguments unavailing. As already explained, the specification explicitly provides that: "[i]t is understood that all the values and intervals disclosed in the process of the present invention must not be intended as absolute. Any value or interval must be understood by the person of ordinary skill in the art as 'about.'" ('915 Patent at 4:57–65). As described above, this portion of the specification indicates that the inventors intended that *any value* disclosed in the '915 Patent, including 2theta values, be construed as "about," so long as the technical effect of the invention is still achieved. And, as further described above, even if, as Defendants argue, this portion of the specification only applies to values disclosed in the process of the present invention, it still supports construing the recited 2theta values in Claim 1 as "about" rather than absolute because the 2theta values were disclosed in the process of the present invention, and as such deviations in those values are within the scope of the present invention. (*Id.*). Accordingly, it would not have been necessary for the inventors to use the word "about" every time they mentioned 2theta values for those values to be understood as "about," since the specification provides that such values should be interpreted as "about." And, as set forth above, other portions of the specification ('915 Patent at 5:34–41, 6:67–7:5 & 9:10–17), as well as the extrinsic evidence indicate that the recited 2theta values should be construed as "about."

Second, Defendants point to other patents listed on the face of the '915 Patent that have explicit words of approximation in claims for recited 2theta values—words of approximation that are notably absent from Claim 1 of the'915 Patent. (Def. Resp. Br. at 31 (citing '199 Patent, '206 Patent & '196 Patent)). Because Claim 1 of the '915 Patent does not include such language, Defendants argue that it should be construed as absolute. (*Id.*) Again, the Court is not persuaded. While the prior art patents that Defendants point to may demonstrate one way in which a patentee

may indicate that 2theta values should be understood as "about," it by no means constitutes the exclusive way to do so. And, as already set forth above, the fact that Claim 1 fails to include any words of approximation before reciting the claimed 2theta values is not sufficient to construe those values as absolute, where other portions of the specification, as well as extrinsic evidence that is consistent with the specification, indicate that those values should be understood as "about." ('915 Patent at 4:57–65, 5:34–41, 6:67–7:5 & 9:10–17)

Third, Defendants argue that the patentee disclaimed rifaximin compositions other than those containing the precise 2theta values recited in Claim 1 during prosecution. (Def. Open. Br. at 34–36; Def. Resp. Br. at 33). For the reasons set forth below, the Court disagrees. Generally speaking, courts indulge a "heavy presumption that claim terms carry their full ordinary and customary meaning, unless the patentee unequivocally imparted a novel meaning to those terms or expressly relinquished claim scope during prosecution." *Omega Eng'g, Inc.*, 334 F.3d at 1323 (internal quotation marks and citations omitted). "When the prosecution history is used solely to support a conclusion of patentee disclaimer, the standard for justifying the conclusion is a high one." *Avid Tech., Inc.*, 812 F.3d at 1045. The Federal Circuit has emphasized that it will not limit a claim term's ordinary meaning based on an ambiguous disclaimer since an ambiguous disclaimer does not advance the patent's notice function or justify public reliance. *SanDisk Corp.*, 415 F.3d at 1287. There is no "clear and unmistakable" disclaimer if a prosecution argument is subject to more than one reasonable interpretation, one of which is consistent with a proffered meaning of the disputed term. *See Golight, Inc.*, 355 F.3d at 1332. The question, therefore, is whether any of the applicant's prosecution arguments to the examiner have no reasonable interpretation other than to disavow rifaximin mixtures beyond those containing the exact 2theta values recited in Claim 1.

During prosecution of the '915 Patent, Claim 1 was rejected as obvious in light of U.S. Patent Number 8,067,429 to Gushurst. ('915 Patent File History at 10). The examiner pointed out that Gushurst disclosed pharmaceutical compositions comprising one or more forms of rifaximin including the α and β forms recited in the '915 Patent. (*Id.* at 12–13 & 15–16). The examiner further noted that Gushurst disclosed a percentage of active ingredient of rifaximin that overlapped with the claimed range of rifaximin α/β in a relative ratio of 85/15±3 in the '915 Patent. (*Id.* at 13 & 16). Based on this disclosure, the examiner concluded that Claim 1 of the '915 Patent was obvious in light of Gushurst. (*Id.*). Claim 1 of the '915 Patent was also rejected as obvious in light of U.S. Patent Number 8,404,704 to Viscomi. (*Id.* at 17). As the examiner noted, Viscomi claimed a method of preparing a pharmaceutical composition of rifaximin, comprising two or more polymorphs selected from the group consisting of form α, form β, and form γ. (*Id.* at 18). Further, according to the examiner, like Gushurst, Viscomi also disclosed a percentage of active ingredient of rifaximin that overlapped with the claimed range of rifaximin in a relative ratio of 85/15±3 in the '915 Patent. (*Id.* at 18–19). Based on this disclosure, the examiner concluded that Claim 1 was obvious in light of Viscomi. (*Id.* at 20–23). In response to these prior art rejections, the applicant amended Claim 1 from "[a] Rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15 ± 3" to add "characterized by an X-Ray spectrum with characteristic 2theta values at (relative intensity): 5.32 (11%), 5.78 (19%), 6.50 (27%), 7.24 (45%), 7.82 (61 %), 8.80 (100%), 10.50 (59%), I 1.02 (35%), 11.58 (32%), 13.08 (20%), 14.42 (26%), 17.32 (48%), 17.68 (93%), 18.58 (79%), 19.52 (61%), 21.04 (52%), 21.60 (30%), and 21.92 (46%)." (*Id.* at 30). In making this amendment, the applicant argued that neither Gushurst nor Viscomi taught "the inventive 85/15±3 mixture of rifaximin α/β forms [with] characteristic 2theta values and relative intensities." (*Id.* at 34–35). Thereafter, the examiner issued a notice of allowance, since Gushurst, the closest

prior art reference, did not specifically teach "a Rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3, characterized by an X-Ray spectrum with characteristic 2theta values as recited in the claim." (*Id.* at 43) (emphasis in original). Accordingly, Defendants argue that because the applicant narrowed Claim 1 to require precisely defined 2theta values to overcome the prior art obviousness rejections, the applicants disavowed any rifaximin compositions beyond those with the exact 2theta values claimed. (Def. Open. Br. at 36).

The Court finds that the applicant did not clearly and unmistakably disclaim rifaximin compositions other than those with the exact 2theta values recited in Claim 1. To be sure, as Defendants point out, in order to overcome the prior art obviousness rejections, the applicant amended Claim 1 to recite the 2theta values now seen in Claim 1. However, "the prosecution history must always receive consideration in context." *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1378 (Fed. Cir. 2008). For example, in *3M Innovative Properties Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1373 (Fed. Cir. 2003), the Federal Circuit held that when a patentee defined a term in the specification, that definition would control over broad statements made during prosecution. *Id.* More specifically, the court stated, "[w]hen the patentee has expressly defined a term in the specification and remarks made to distinguish claims from the prior art are broader than necessary to distinguish the prior art, the full breadth of the remark is not a clear and unambiguous disavowal of claim scope as required to depart from the meaning of the term provided in the written description." *Id.* Here, as Plaintiff points out, the amendment of Claim 1 to recite certain 2theta values must still receive consideration in context of the specification, which indicated that "all the values and intervals disclosed in the process of the present invention must not be intended as absolute" but rather "must be understood by the person of ordinary skill in the art as 'about.'" ('915 Patent at 4:57–65); (Pl. Resp. Br. at 30). As described

above, this portion of the specification suggests that the inventors intended that *any value* disclosed in the '915 Patent, including 2theta values, be construed as "about," so long as the technical effect of the invention is still achieved. And, as further described above, even if, as Defendants argue, this portion of the specification only applies to values disclosed in the *process of the present invention*, it still indicates that the recited 2theta values in Claim 1 should be understood as "about" rather than absolute because those values were disclosed in the process of the present invention. As such, a deviation in those values is within the scope of the present invention—not just within the scope of the process of the present invention. ('915 Patent at 4:57–65 (emphasis added)). Though the patentee's decision to amend Claim 1 to recite certain 2theta values could arguably be read as disavowing rifaximin compositions beyond those with the exact 2theta values recited in Claim 1, the Court declines to find such a clear and unambiguous disavowal of claim scope, where, as in *3M,* the patentee still indicated that those values should be understood as "about" in the written description. *3M Innovative Properties Co.*, 350 F.3d at 1373.

Further, during prosecution, the applicant at no point clearly and unmistakably indicated that the 2theta values added to Claim 1 were absolute. As recounted above, to overcome the prior art rejections, the applicant of the '915 Patent amended Claim 1 to add certain characteristic 2theta values. However, as Plaintiff points out, one interpretation of the prosecution history is that the applicant was merely better defining the rifaximin mixture of the invention by adding in 2theta values, by which the mixture could be characterized, rather than indicating that those values needed to be exact. (Pl. Resp. Br. at 29–30). In fact, the applicant amended Claim 1 such that the claimed rifaximin polymorphic mixture of α/β form need only be "*characterized by*" the recited 2theta values. ('915 Patent File History at 30; '915 Patent at 10:50–57). The applicant's decision to include the term "characterized by," suggests that the recited 2theta values need not necessarily be

understood as absolute, so long as the claimed polymorphic mixture could still be identified by reference to those values. *See, e.g., Kowa Co., Ltd.*, 2017 WL 10667089, at *37–39; *Eisai Co*, 2015 WL 1228958, at *8. This is particularly true given that the patentee still indicated that those values should be understood as "about" in the written description. Likewise, when distinguishing the amended Claim 1 from Gushurst and Viscomi, the applicant merely provided that neither of those references recited the "*characteristic* 2theta values" as recited in Claim 1, again suggesting that the recited 2theta values need not necessarily be understood as absolute, so long as the claimed polymorphic mixture could still be characterized by reference to those values. ('915 Patent File History at 34–35). And here, as discussed above, the specification indicates, in Figure 4 and Figure 5, that the "rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3," as disclosed by the invention, can be identified by reference to the 2theta values depicted in both Figure 4 and Figure 5 even though those values are slightly different. ('915 Patent at 4:66–5:41 & 6:65–7:5). Further, as discussed above, the USP states that when using XRPD to compare a known material ("reference") with an unknown material ("specimen"): "[t]he agreement in the 2[theta]-diffraction angles between specimen and reference is within 0.2° for the *same crystal form*." (USP 941 at 507). Accordingly, because it was understood at the time of the invention that there is experimental error associated with X-ray diffraction and that 2theta values for the same crystal will vary within 0.2 degrees from one experimental run to the next, the extrinsic evidence also indicates that the claimed rifaximin polymorphic mixture of α/β form could still be "characterized by" reference to the recited 2theta values even if they varied within normal experimental error. (Pl. Open. Br. at 35–36 (citing USP 941 at 507 & Swift Decl. ¶¶ 78–79)).

Accordingly, though the applicant amended Claim 1 to recite certain 2theta values to overcome obviousness rejections, the Court finds that the prosecution history is at least ambiguous

with regards to whether the applicant clearly and unmistakably indicated that the invention could not include rifaximin mixtures beyond those with the *exact* 2theta values recited in Claim 1. In sum, the statements in the prosecution history relied on by Defendants, while arguably subject to the interpretation Defendants give them, can also be reasonably understood as merely better defining the rifaximin mixture of the invention by adding in 2theta values, by which the mixture could be characterized, rather than indicating that those values needed to be exact. This is particularly true given that the patentee still indicated that those values should be understood as "about" in the written description. As such, the Court will not construe the recited 2theta values in Claim 1 as absolute based on an ambiguous disclaimer. *SanDisk Corp.*, 415 F.3d at 1287.

The court's decision in *AstraZeneca AB v. Andrx Labs, LLC*, No. 14-8030, 2017 WL 111928, at *48, (D.N.J. Jan. 11, 2017), is further instructive on this point. In *Andrx*, the court construed a claim which read as follows: "[t]he magnesium salt of S-omeprazole trihydrate, wherein the compound is characterized by the following major peaks in its X-ray diffractogram." *Id.* at *6–7. During prosecution, the applicant had amended the contested claim to recite the X-ray diffractogram peak values to overcome a prior art rejection, noting that "[t]he claimed magnesium salt of S-omeprazole trihydrate" is "uniquely characterized by an X-ray powder diffractogram which distinguishes the claimed compound from any other form of the magnesium salt of S-omeprazole." *Id.* at *47. Despite this amendment, the Court construed the disputed term "characterized by the following major peaks in its X-ray diffractogram" to mean "having each of the referenced major peaks in its X-ray powder diffractogram within normal experimental error." *Id.* The Court declined to adopt a construction that would require an exact match to each value as too rigid, particularly where the parties and their experts agreed "that there will be some range of normal experimental error in an X-ray powder diffractogram." *Id.* at * 48. Likewise, here, in light

of the intrinsic and extrinsic record, the Court also declines to construe the recited 2theta values as absolute, based on an ambiguous prosecution disclaimer, as such a construction would be too rigid.

Citing to the Federal Circuit's decision in *Univ. of Mass. v. L'Oreal S.A.*, 36 F.4th 1374, 1379 (Fed. Cir. 2022), Defendants argue that even if the applicant's statements during prosecution of the '915 Patent do not rise to the level of disclaimer or disavowal, they necessarily still inform the construction off the disputed claim term. (Def. Open. Br. at 37). However, while prosecution history statements inform claim construction, the mere fact that the applicant amended Claim 1 to include certain 2theta values does not mean that those values were absolute, particularly in light of the fact that Claim 1 was amended such that the claimed rifaximin polymorphic mixture of α/β form need only be "*characterized by*" the recited 2theta values, and that the specification still emphasized that "all the values and intervals disclosed in the process of the present invention must not be intended as absolute" but rather "must be understood by the person of ordinary skill in the art as 'about.'" ('915 Patent at 4:57–65).

Fourth, with regards to the extrinsic evidence, Defendants argue that even if it was well understood at the time of the invention that 2theta values typically vary within 0.2 degrees, Claim 1 should still be construed as absolute, rather than "about," because it makes little sense mathematically to express a value to *hundredths* if the values were intended to have a margin of error of plus or minus two *tenths*. (Def. Resp. Br. at 39). The Court disagrees. To start, the Court does not rely solely on extrinsic evidence in finding that the recited 2theta values in Claim 1 should be construed as "about." Rather, as described above, the intrinsic record, which is primary in the Court's analysis, indicates that the 2theta values should be understood as "about" rather than absolute, regardless of the fact that the extrinsic evidence indicates that the experimental error associated with 2theta values is expressed to plus or minus two tenths and the 2theta values as

claimed are expressed to hundredths. (*See, e.g.*, '915 Patent at 4:57–65, 5:34–41, 6:65–7:12 & 9:10–17). Nevertheless, the extrinsic evidence, as recited in the USP, is consistent with the intrinsic record and supports construing the recited 2theta values as "about." Even though the 2theta values in Claim 1 are reported to hundredths, the Court does not find it inappropriate to construe them as about, in light of the extrinsic evidence. This is so even though the margin of error in the industry was recited to only plus or minus two tenths. (USP 941 at 507). Plaintiff's expert, Dr. Swift, indicated that a POSA could reasonably apply a margin of error of plus or minus two tenths even if the 2theta values are expressed to the hundredths. For example, she testified that if a peak is recited at 5.32 she would consider a peak that is between 5.12 and 5.52 to be within the margin of error that is recited in the USP. (Swift Dep. at 49:25–51:3).

Defendants' expert, Dr. Myerson, also appears to have confirmed this understanding. More specifically, Plaintiff points out that in connection with a 2011 litigation, Defendants' expert Dr. Myerson submitted a declaration ("2011 Declaration") arguing that the following claim, which refers to measurements obtained through X-ray diffraction, should be interpreted to include normal experimental error: "characteristic peaks at interplanar spacings (d)." (Pl. Resp. Br. at 32 (citing D.E. No. 95-4 at 16)). Values at interplanar spacings (d), or "d-spacing" values, are related to 2theta values according to Bragg's Law, $n\lambda = 2d\sin\theta$, and can also be used to characterize crystalline samples. (Swift Decl. ¶ 52; Myerson Decl. ¶ 43). While d-spacing values cannot be measured, they can be calculated using 2theta values. (Myerson Dep. at 92:14–19). In his 2011 Declaration, Dr. Myerson argued that "characteristic peaks at interplanar spacings (d)" should be construed to account for experimental error, because at the time of the invention, it was well recognized that there is a +/0.10 or +/0.20 range of experimental error associated with the 2theta values in X-ray powder experiments, which are used to calculate d-spacing values. (D.E. No. 95-

4 ¶¶ 64–65). And Plaintiff points out that Dr. Myerson argued that there was an experimental error of ± 0.10–0.20, even though the d-spacing values were recited to hundredths. *See also H. Lundbeck A/S*, 2019 WL 3206016, at *3–4 (finding that claim term should allow for experimental error even though 2theta values were reported to hundredths and error rate was reported to only tenths (U.S. Patent No. 8,722,684 at 4:50–66)). As such, the Court finds Defendants' argument unavailing.[21]

Fifth, Defendants argue that the Court should construe the 2theta values as absolute because adding the word "about" into the claim would require further construction, since Plaintiff does not purport to define what "about" means in numerical terms. (Def. Open. Br. at 39). In response to Defendants' argument, Plaintiff states that including "about" in Claim 1 would not require further construction because "about" has been construed repeatedly to be a term a POSA would understand. (Pl. Resp. Br. at 31 (citing *Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1369–70 (Fed. Cir. 2005)). And at the *Markman* hearing, Plaintiff contended that the term "about" should merely be understood in accordance with the specification's guidance which provides that "[t]he term 'about', as currently intended, means that any value herein disclosed not necessarily must be exactly taken per se, but that a deviation from this value is within the scope of the present invention, provided that the technical effect herein disclosed is achieved. (*Markman* Hr'g Tr. at 80:18–81:14; 135:23–136: 5; '915 Patent at 4:57–65). The Court agrees with Plaintiff.

[21] To be sure, later in her deposition, when asked if it would make sense to express a value to two decimal places of precision if the margin of error is plus or minus two tenths, Dr. Swift stated, "I have seen in other cases where people have rounded numbers from two decimal places down to one decimal place, and then when you apply the plus or minus [point] two, you wind up with a very different range than where you would have been if you had kept that second decimal place." (Swift Dep at 69:4–9). However, as described above, the intrinsic record, which is primary in the Court's analysis, indicates that the 2theta values should be understood as "about" rather than absolute, regardless of the fact that the extrinsic evidence indicates that the experimental error associated with 2theta values is expressed to plus or minus two tenths and the 2theta values as claimed are expressed to hundredths. (*See, e.g.,* '915 Patent at 4:57–65, 5:34–41, 6:65–7:12 & 9:10–17). And, as discussed, other extrinsic evidence indicates that it would not be inappropriate to construe the recited 2theta values as about, even though the margin of error in the industry was recited to only plus or minus two tenths.

"[T]he word 'about' does not have a universal meaning in patent claims, and . . . the meaning depends on the technological facts of the particular case." *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995) (citation omitted). The intrinsic record does not provide guidance for further construing "about" with respect to a specific numerical range for the claimed 2theta values. Rather, as discussed, the specification indicates that those values should be understood as "about" rather than by reference to a specific range and explains that "[t]he term 'about', as currently intended, means that any value herein disclosed not necessarily must be exactly taken per se, but that a deviation from this value is within the scope of the present invention, provided that the technical effect herein disclosed is achieved." ('915 Patent at 4:57–65). As such, although the extrinsic evidence indicates that 2theta values typically vary within 0.2 degrees, the Court declines to further construe "about" with respect to those values given that the intrinsic record only provides that those values should be understood as "about" and specifically explains how "about" should be understood in the context of the invention. Finally, the Federal Circuit has cautioned courts against giving a claim whatever additional precision is necessary to facilitate a comparison between the claim and the accused product under the rubric of claim construction. *PPG Industries v. Guardian Industries Corp.*, 156 F.3d 1351, 1355 (Fed. Cir. 1998). Rather, after the court has defined the claim with whatever specificity is warranted by the claim language and the evidence bearing on the proper construction, as it has here in finding that the recited 2theta values should be construed as "about" in accordance with the specification, the task of determining whether the construed claim reads on the accused product is for the finder of fact. *Id.* As such, the Court declines to further construe "about" with respect to a specific range.

Sixth, Defendants argue that if Plaintiff does not modify its definition of "about" with respect to 2theta values to encompass a specific range or margin of error, the claim will be

indefinite, as a person of ordinary skill would not be informed of the scope of the claim with reasonable certainty under Plaintiff's proposed construction. (Def. Resp. Br. at 37 n.6). The Court will not construe the recited 2theta values as absolute as Defendants suggest based on this argument. As the Federal Circuit has emphasized, "[c]laim terms should be given their plain and ordinary meaning to one of skill in the art at the relevant time and cannot be rewritten by the courts to save their validity." *Hill-Rom Servs., Inc.*, 755 F.3d at 1374. As such, given that the sum of the intrinsic and extrinsic evidence indicates that the recited 2theta values should be construed as "about" and the specification explains how "about" should be understood in the context of the invention, the Court will not rewrite Claim 1 to preserve its validity. And while it is possible that the Court's construction may lead to issues with Claim 1's definiteness, the Court finds that any indefiniteness challenges can be better addressed at a later time with a more developed record. *See Alcon Research, Ltd.*, 2011 WL 3901878, at *16.

v. The Intrinsic Record Supports Construing the Recited Relative Intensity Values as "About"

Relative Intensities. The Court will now consider whether the recited relative intensity values should be construed as "about" or absolute. In resolving this dispute, the Court begins again with the words of Claim 1. *Teleflex, Inc.*, 299 F.3d at 1324. On the one hand, as Defendants point out, Claim 1 does not use an error range or any words of approximation before reciting the claimed relative intensity values. (Def. Resp. Br. at 31). This is in contrast to other values appearing in the claims of the '915 Patent which do have an accompanying error range, suggesting that the recited relative intensity values should be construed as absolute. (*See, e.g.*, '915 Patent at 10:50–51 ("Rifaximin polymorphic mixture of α/β form in a relative ratio of *85/15±3*) (emphasis added); *id.* at 11:6–7 ("to reach a final water content of *6±2%*") (emphasis added)). Nevertheless, other portions of Claim 1 support construing the recited relative intensity values as "about." More

specifically, Claim 1 of the '915 Patent covers a range of relative ratios of the α and β polymorphic forms of rifaximin— "[a] rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3." ('915 Patent at 10:50–51 (emphasis added)). As Plaintiff points out, "given the claimed range of relative ratios of the α and β polymorphic forms of rifaximin" a POSA would have understood that the recited relative intensity values could not reasonably be considered absolute. (Pl. Open. Br. at 30–31). This is because, as the ratio of α polymorph to β polymorph in the rifaximin mixture changes, the relative intensity values corresponding to that mixture may also change. This principle is illustrated in the specification itself. For example, the specification describes a procedure for creating a calibration curve by mixing the α polymorph and β polymorph in known relative ratios of 80/20 and 90/10 and then measuring the resulting 2theta values and peak intensities by X-ray diffraction. ('915 Patent at 7:67–8:15). The calibration curve is then prepared by dividing the intensity of the resulting β peak by the intensity of the α peak at specific 2theta locations for the 80/20 and 90/10 α/β ratios, resulting in the figure below. (*Id.*)

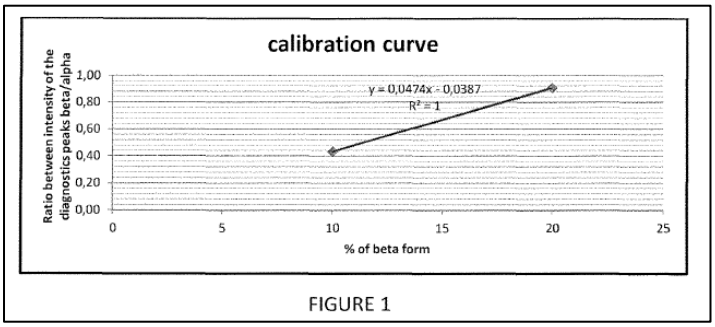

FIGURE 1

('915 Patent at Figure 1). This Figure indicates that the absolute intensity of β and α peaks (with the intensity of β divided by the intensity of α plotted on the y axis) changes based on the relative ratio of β to α polymorph in the rifaximin mixture (plotted on the x-axis). Because relative intensity values are calculated based on the absolute intensity of a given peak relative to the absolute intensity of the highest peak in a diffractogram (Swift Decl. ¶ 55), this Figure indicates that relative intensity values corresponding to a given rifaximin mixture may change as the relative

ratio of β to α polymorph in the mixture changes. And at the *Markman* hearing, both parties agreed that this was true. (*Markman* Hr'g. Tr. at 101:10–20, 105:1–4 & 106:17–24). Accordingly, because Claim 1 covers a range of relative ratios of the α and β polymorphic forms of rifaximin, claim context indicates that there is some variability built into the recited relative intensity values as well, since relative intensity values may change as the range of relative ratios of α and β polymorphs in the rifaximin mixture change. In sum, the Court finds that claim context, as informed by the specification, supports construing the recited relative intensity values as "about."

Further, though Claim 1 does not include any words of approximation before reciting the claimed relative intensity values, other portions of the specification of the '915 Patent also indicate that the recited relative intensity values should be construed as "about." To start, as has been previously discussed, the specification of the '915 Patent explicitly provides:

> It is understood that all the values and intervals disclosed in the process of the present invention must not be intended as absolute. Any value or interval must be understood by the person of ordinary skill in the art as 'about.' The term 'about', as currently intended, means that any value herein disclosed not necessarily must be exactly taken per se, but that a deviation from this value is within the scope of the present invention, provided that the technical effect herein disclosed is achieved.

('915 Patent at 4:57–65 (emphasis added)). As described above with regards to the 2theta values, this portion of the specification suggests that the inventors intended that *any value* disclosed in the '915 Patent, including relative intensity values, be construed as "about," so long as the technical effect of the invention is still achieved. Further, even though Defendants again argue that this passage only applies to values disclosed in the *process of the present invention* it still supports construing the recited relative intensity values in Claim 1 as "about" rather than absolute. (Def. Open. Br. at 37 & Def. Resp. Br. at 33). More specifically, after specifying that the values and intervals disclosed in the process of the present invention should not be intended as absolute, the

specification goes on to describe a "preferred embodiment" of the process of the present invention that results in the final rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3. ('915 Patent at 4:66–5:41). As Plaintiff pointed out during the *Markman* hearing, at multiple points during this process, the specification characterizes intermediate products—those that are formed before the final rifaximin polymorphic mixture of α/β form is recovered—by X-ray diffraction, indicating that X-ray diffraction is part of the process of the present invention. ('915 Patent at 5:21–5:33; *Markman* Hr'g Tr. at 94:22–95:15). Because relative intensity values are calculated as a result of X-ray diffraction, the specification indicates that those values are disclosed in the process of the present invention and as such should be understood as "about" rather than absolute. (*Markman* Hr'g Tr. at 94:22–95:15). Further, because the final step of the "preferred embodiment" of the process of the present invention involves recovering a "Rifaximin α/β polymorphic mixture" with characteristic relative intensity values as recited in Claim 1, those values are disclosed in the process of the present invention. ('915 Patent at 5:34–41). And as the specification states, "[i]t is understood that all the values and intervals disclosed in the process of the present invention must not be intended as absolute" and "a deviation from [these] value[s] is *within the scope of the present invention*," not just within the scope of the *process* of the present invention. ('915 Patent at 4:57–65 (emphasis added)). As such, this portion of the specification supports construing the recited relative intensity values as "about," rather than absolute.

Figure 4 and Figure 5 also indicate that the relative intensity values as recited in Claim 1 should be construed as "about." (Pl. Open. Br. at 31). As set forth above, the relative intensity values that correspond to the rifaximin α/β polymorphic mixture in a relative ratio of 87/13, as disclosed in Figure 4, are the following: 5.32 (11%), 5.78 (19%), 6.50 (27%), 7.24 (45%), 7.82 (61%), 8.80 (100%), 10.50 (59%), 11.02 (35%), 11.58 (32%), 13.08 (20%), 14.42 (26%), 17.32

(48%), 17.68 (93%), 18.58 (79%), 19.52 40 (61%), 21.04 (52%), 21.60 (30%), 21.92 (46%). ('915 Patent at 5:37–41 & 9:13–17). The relative intensity values that correspond to the rifaximin α/β polymorphic mixture in a relative ratio of 85/15±3 that has been formed into uncoated tablets, as disclosed in Figure 5, are the following: 5.28 (15%), 5.78 (23%), 6.52 (46%), 7.26 (47%), 7.88 (75%), 8.82 (42%), 10.52 (46%), 11.02 (45%), 11.58 (40%), 13.12 (37%), 14.48 (42%), 17.38 (56%), 17.72 (62%), 18.62 (93%), 19.54 (72%), 21.10 (87%), 21.64 (82%), 22.00 (100%). (*Id.* at 6:67–7:5). The specification also discloses the diagnostic peaks and relative intensity values of those peaks that correspond to the five excipients that have been added to the rifaximin α/β polymorphic mixture in a relative ratio of 85/15±3, as disclosed in Figure 5, to form uncoated tablets as follows: "19.10 (50%) and 28.72 (40%) for talc; 22.36 (99%) microcrystalline cellulose; 21.10 (87%) for glycerol palmitostearate; 45.74 (36%) sodium starch glycolate; hydrate silicon dioxide is amorphous and does not present diffraction Peaks." (*Id.* at 7:5–12). As Plaintiff points out (Pl. Open. Br. at 31–32), though both Figure 4 and Figure 5 embody "[a] rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3," as disclosed by the invention, they each possess 2theta values and relative intensity values that differ. (*Compare* '915 Patent at 6:67–7:5 *with id.* at 5:34–41 & 9:10–17). And according to the specifications, both Figure 4 and Figure 5 represent rifaximin mixtures that are preferred embodiments of the present invention prepared according to preferred embodiments of the process of the present invention. ('915 Patent at 4:66–5:41 & 6:27–7:12). In fact, as stated above, if the Court adopted Defendants' construction, that construction would exclude from the scope of Claim 1 the rifaximin mixture embodied in Figure 5. Such a construction, however, would improperly exclude a preferred embodiment from the scope of the claims in the '915 Patent. *Vitronics Corp.,* 90 F.3d at 1583. Accordingly, because the specification discloses variability in the relative intensity values that correspond to "[a] rifaximin polymorphic

mixture of α/β form in a relative ratio of 85/15±3" of the invention, the specification's disclosure indicates that the relative intensity values recited in Claim 1 should be construed as "about." This is consistent with the disclosure of the '915 Patent which, as discussed above, indicates that deviations in relative intensity values, disclosed in the process of the present invention, are within the scope of the invention. ('915 Patent at 4:57–65).

Defendants again contest this interpretation and point out that Figure 4 and Figure 5 are diffractograms of two fundamentally different samples. (Def. Resp. Br. at 33–34 n.5). More specifically, they assert that Figure 5 includes not only a rifaximin α/β polymorphic mixture, but also different excipients unlike Figure 4 which contains no excipients. (*Id.* (citing '915 Patent at 10:20–36)). Defendants assert that the presence of excipients is reflected in different intensities in Figure 5. And because relative intensity is the intensity "relative to the most intense peak," Defendants argue that all of the relative intensity values of the uncoated tablet as shown in Figure 5 will be significantly different from the relative intensities shown in Figure 4. (*Id.*). Accordingly, they assert that there is no basis for Plaintiff's argument that the differences between Figures 4 and 5 support its contention that the recited relative intensity values should be construed to include experimental error. (*Id.*). However, Plaintiff does not ask the Court to construe the recited relative intensity values as within "experimental error." Rather, Plaintiff asks the Court to construe those values as "about." And here, the differences in the relative intensity values of Figure 4 and Figure 5, which both embody "[a] rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3," and represent preferred embodiments of the invention support construing the recited relative intensity values in Claim 1 as "about."[22] This is consistent with the disclosure of the '915

[22] Notably, it is not even clear from the specification that the differences in the relative intensity values between Figure 4 and Figure 5 are attributable to the excipients. During the *Markman* hearing, Plaintiff explained that relative intensity values may change based on the presence of excipients in a composition, because if an excipient produces the most intense peak in a diffractogram, all of the relative intensity values—which are calculated based on the

Patent which, as discussed above, indicates that the relative intensity values, which are disclosed in the process of the present invention, must be understood as "about." ('915 Patent at 4:57–65).

vi. The Extrinsic Record is Consistent with the Intrinsic Record and Supports Construing the Recited Relative Intensities as "About"

Further, the extrinsic evidence is consistent with the intrinsic evidence and also supports construing the recited relative intensity values as "about," rather than absolute. More specifically, as with the 2theta values, the 2014 edition of the USP provides that when using XRPD to compare a known material ("reference") with an unknown material ("specimen"): "relative intensities between specimen and reference may vary considerably due to preferred orientation effects." (USP 941 at 507). Likewise, Dr. Swift testified that when comparing XRPD data between specimen and reference, intensities "vary based on the sample orientation and/or morphology of crystals, which could depend on how one produces, formulates, and/or tablets the crystalline material." (Swift Decl. ¶ 59). As such, the extrinsic evidence, which is consistent with the intrinsic record in this case, indicates that a person skilled in the art would not have required any words of approximation, either in the specification or in the claims, to understand that the recited relative intensity values should be construed as "about." *Verve, LLC,* 311 F.3d at 1119; *see Kowa Co., Ltd.*, 2017 WL 10667089, at *37 (finding that claim language "characteristic [XRPD] pattern with characteristic peaks" does not require exact match of all relative intensities where it was

intensity of a peak in relation to the highest peak—will necessarily change as a result. (*Markman* Hr'g. Tr. at 120:4–20). Here, however, it appears, based on the specification, that the highest peak in the diffractogram of Figure 5 is attributable to the α/β polymorphic mixture, rather than to any of the excipients. ('915 Patent at 7:4–11) (indicating that the most intense peak is present at 2theta of 22.00 (100%), and not at any of the diagnostic 2theta values attributable to the excipients recited thereafter). As such, the differences in the relative intensity values between Figure 4 and Figure 5 could very well be attributable to experimental error. Regardless, however, the specification of the '915 Patent still indicates that the relative intensity values, which are disclosed in the process of the present invention, must be understood as "about." ('915 Patent at 4:57–65).

understood that variation of relative intensities was to be expected in experimental studies on different instruments and sample preparations).[23]

vii. The Court is Not Convinced by Defendants' Contrary Arguments

Defendants' remaining arguments to the contrary are unavailing. *First,* Defendants argue that Plaintiff's proposed construction would make little sense as applied to the recited relative intensity values, specifically. They argue that this is because "relative intensities" are a calculated value—the height of a given peak relative to the height of the highest peak in a diffractogram—and accordingly are not "at" anywhere, in contrast to 2theta peaks which are plotted at locations in an X-ray diffractogram. (Def. Resp. Br. at 35). As such, they contend that "at" as recited in Claim 1, which covers "A Rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3, characterized by an X-Ray spectrum with characteristic 2theta values at (relative intensity)," applies only to 2theta values and not relative intensity values. (*Id.*). The Court is not persuaded. To start, as discussed, the specification suggests that the inventors intended that *any value* disclosed in the '915 Patent, including relative intensity values disclosed in the process of the present invention, be construed as "about," so long as the technical effect of the invention is achieved. ('915 Patent at 4:57–65). Further, as Dr. Swift explained in her deposition, it would make sense to apply the term "about" to relative intensity values, because even though a relative

[23] To support their argument that the term "about" should not be added into Claim 1 to modify the recited 2theta values and relative intensity values, Defendants cite to the Federal Circuit's decision in *Takeda Pharmaceuticals Co. v. Zydus Pharmaceuticals USA, Inc.*, 743 F.3d 1359 (Fed. Cir. 2014). (Def. Open. Br. at 39). In *Takeda*, the Federal Circuit rejected the district court's construction of "400 μm" in a claim term reciting "fine granules having an average particle diameter of 400 μm or less," that permitted a 10% margin of error in particle size measurement. The Federal Circuit rejected that construction because the intrinsic record demonstrated that the inventors knew to use the term "about" in claim language to allow for a margin of error in numerical measurements but chose not to use "about" in the disputed claim term. *Id.* at 1365. The Court, however, finds *Takeda* distinguishable. In *Takeda* the specification made clear that the size value given in the disputed term was intended to serve as a clear dividing line between "conventional" granules and "fine" granules, and was important to achieving the patent's objective of avoiding a feeling of roughness in the patient's mouth upon disintegration. *Id.* at 1364. In other words, the specification indicated the importance of the exact value. Here, there is no suggestion in the '915 Patent that the recited 2theta values and relative intensity values given in Claim 1 are intended to be interpreted any more precisely than a POSA normally would interpret them in light of the intrinsic and extrinsic record, as described above.

intensity value is not a measurement of a location on a diffractogram in the same way that a 2theta value is, it describes the intensity of a peak at a particular location in relation to the highest peak. (Swift Dep. at 47:16–20). In other words, it is tied to the peak that exists *at* a given location. (*Id.*). As such, the Court finds Defendants' argument unavailing.

Second, Defendants argue that the applicant of the '915 Patent disclaimed rifaximin compositions other than those containing the precise relative intensity values recited in Claim 1 during prosecution. (Def. Open. Br. at 34–36; Def. Resp. Br. at 33). As stated above with respect to the recited 2theta values, the Court finds that the applicant did not clearly and unmistakably disclaim rifaximin compositions other than those with the exact relative intensity values recited in Claim 1. To be sure, as Defendants point out, during prosecution of the '915 Patent, the applicant amended Claim 1 to recite the relative intensity values in Claim 1. However, as stated above "the prosecution history must always receive consideration in context." *Computer Docking Station Corp..*, 519 F.3d at 1378. Consistent with the Federal Circuit's decision in *3M*, as discussed above, the amendment of Claim 1 to recite certain relative intensity values must still be read in light of the specification, which provided that "[i]t is understood that all the values and intervals disclosed in the process of the present invention must not be intended as absolute." ('915 Patent at 4:57–65); (Pl. Resp. Br. at 30). As described above, this portion of the specification suggests that the inventors intended that *any value* disclosed in the '915 Patent, including relative intensity values, be construed as "about," so long as the technical effect of the invention is achieved. And, as further described above, even if, as Defendants argue, this portion of the specification only applies to values disclosed in the *process of the present invention*, it still indicates that the recited relative intensity values in Claim 1 should be understood as "about" because those values were disclosed in the process of the present invention. ('915 Patent at 4:57–65 (emphasis added). Accordingly,

though the applicant's decision to amend Claim 1 to recite certain relative intensity values could arguably be read as disavowing rifaximin compositions beyond those with the exact relative intensity values recited in Claim 1, the Court declines to find such a clear and unambiguous disavowal of claim scope, where, as in *3M*, the patentee still indicated that those values should be understood as "about" in the specification. *3M Innovative Properties Co.*, 350 F.3d at 1373.

Further, as recounted above, though the applicant of the '915 Patent amended Claim 1 to add certain characteristic relative intensity values to overcome the prior art obviousness rejections, the applicant at no point clearly and unmistakably indicated that those values were absolute. As Plaintiff points out, one interpretation of the prosecution history is that the applicant was merely better defining the rifaximin mixture of the invention by adding in relative intensity values, by which the mixture could be characterized, rather than indicating that those values needed to be exact. (Pl. Resp. Br. at 29–30). In addition, even after amending Claim 1, the Claim still covered a range of relative ratios of the α and β polymorphic forms of rifaximin—"[a] rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15***±3***." ('915 Patent at 10:50–51). As explained above, because Claim 1 covers a range of relative ratios of the α and β polymorphic forms of rifaximin, claim context indicates that there is variability built into the recited relative intensity values as well, since relative intensity values corresponding to the rifaximin mixture may change as the range of relative ratios of α and β polymorphs in the rifaximin mixture change. ('915 Patent at Figure 1 & 7:67–8:15). Accordingly, though the applicant amended Claim 1 to include certain relative intensity values, the fact that the Claim 1 still covered a range of relative ratios of the α and β polymorphic forms of rifaximin indicates that the applicant did not clearly disclaim rifaximin compositions other than those with the exact relative intensity values recited in Claim 1.

Further, as stated above, Claim 1 was amended such that the claimed rifaximin polymorphic mixture of α/β form need only be "*characterized by*" the recited relative intensity values. ('915 Patent at 10:50–57 (emphasis added)). This suggests that the recited relative intensity values need not necessarily be understood as absolute, so long as the claimed polymorphic mixture could still be identified by reference to those values. This is particularly true given that the patentee still indicated that those values should be understood as "about" in the written description. Further, when distinguishing the amended Claim 1 from Gushurst and Viscomi, the applicant merely provided that neither of those references recited the "*characteristic* . . . relative intensities" as recited in Claim 1, again suggesting that the recited relative intensity values need not necessarily be understood as absolute, so long as the claimed polymorphic mixture could still be characterized by reference to those values. ('915 Patent File History at 34–35). And here, as discussed above, the specification indicates, in Figure 4 and Figure 5 that the "rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3," as disclosed by the invention, can be identified by reference to the relative intensity values depicted in both Figure 4 and Figure 5 even though those values are different. ('915 Patent at 5:37–41 & 6:67–7:5). Further, as discussed above, the USP states that when using XRPD to compare a known material ("reference") with an unknown material ("specimen"), relative intensities between specimen and reference may vary considerably due to preferred orientation effects." (USP 941 at 507). Because it was understood at the time of the invention that there is variability associated with the measurement of relative intensity values, the extrinsic evidence indicates that the claimed rifaximin polymorphic mixture of α/β form could still be "*characterized by*" reference to the recited relative intensity values even if they varied. (Pl. Open. Br. at 35–36 (citing USP 941 at 507 & Swift Declaration ¶¶ 78–79) (emphasis added)); *See, also Kowa Co., Ltd.*, 2017 WL 10667089, at *37. Accordingly, though

the applicant specifically amended Claim 1 to recite certain relative intensity values to overcome prior art obviousness rejections, the Court finds that the prosecution history is at least ambiguous with regards to whether the applicant clearly and unmistakably indicated that the invention could not include rifaximin compositions beyond those with the exact relative intensity values recited in Claim 1. As such, the Court will not construe the recited relative intensity values in Claim 1 as absolute based on an ambiguous disclaimer. *SanDisk Corp.*, 415 F.3d at 1287.[24]

Third, Defendants argue that the Court should construe the relative intensity values as absolute because adding the word "about" into the claim would require further construction, since Plaintiff does not purport to define what "about" means in numerical terms. (Def. Open. Br. at 39). In response to Defendants' argument, Plaintiff states that including "about" in Claim 1 would not require further construction because "about" has been construed repeatedly to be a term a POSA would understand. (Pl. Resp. Br. at 31 (citing *Merck & Co., Inc.*, 395 F.3d at 1369–70)). And at the *Markman* hearing, Plaintiff contended that the term "about" should merely be understood in accordance with the specification's guidance which explains that "[t]he term 'about', as currently intended, means that any value herein disclosed not necessarily must be exactly taken per se, but that a deviation from this value is within the scope of the present invention, provided that the technical effect herein disclosed is achieved. (*Markman* Hr'g Tr. at 135:23–136: 5; '915 Patent at 4:57–65). The Court agrees with Plaintiff. "[T]he word 'about' does not have a universal meaning in patent claims, and . . . the meaning depends on the technological facts of the particular

[24] Citing to the Federal Circuit's decision in *Univ. of Mass. v. L'Oreal S.A.*, 36 F.4th 1374, 1379 (Fed. Cir. 2022), Defendants argue that even if the applicant's statements during prosecution of the '915 Patent do not rise to the level of disclaimer or disavowal, they necessarily still inform the construction of the disputed claim term. (Def. Open. Br. at 37). However, as stated above, while prosecution history statements inform claim construction, the mere fact that the applicant amended Claim 1 to include certain relative intensity values does not mean that those values were absolute, particularly in light of the fact that Claim 1 still covered a range of relative ratios of α and β polymorphs and was amended such that the claimed rifaximin polymorphic mixture of α/β form need only be "*characterized by*" the recited relative intensity values, not that it be confined to those exact values.

case." *Pall Corp.*, 66 F.3d at 1217 (citation omitted). The intrinsic record does not provide guidance for further construing "about" with respect to a specific numerical range for the claimed relative intensity values. Rather, as discussed, the specification indicates that those values should be understood as "about" and explains that "[t]he term 'about', as currently intended, means that any value herein disclosed not necessarily must be exactly taken per se, but that a deviation from this value is within the scope of the present invention, provided that the technical effect herein disclosed is achieved." ('915 Patent at 4:57–65). As such, the Court declines to further construe "about" with respect to a specific numerical range as to the relative intensity values given that the intrinsic record only provides that those values should be understood as "about" and explains how "about" should be understood in the context of the invention. Finally, the Federal Circuit has cautioned courts against giving a claim whatever additional precision is necessary to facilitate a comparison between the claim and the accused product under the rubric of claim construction. *PPG Industries*, 156 F.3d at 1355. Rather, after the court has defined the claim with whatever specificity is warranted by the claim language and the evidence bearing on the proper construction, as it has here in finding that the recited relative intensity values should be construed as "about," the task of determining whether the construed claim reads on the accused product is for the finder of fact. *Id.* As such, the Court declines to further construe "about" with respect to a specific range.

Fourth, Defendants argue that if Plaintiff does not modify its definition of "about" with respect to relative intensity values to encompass a specific range or margin of error, the claim will be indefinite. Defendants point out that Dr. Swift was not able to identify a numerical boundary that would apply to the relative intensity values, instead saying that "you know it when you see it." (Def. Resp. Br. at 36 (citing Swift Dep. at 54:17–55:24)). And the USP does not seem to provide more helpful guidance, simply stating that "relative intensities between specimen and

reference may vary considerably." (USP 941 at 507). Accordingly, Defendants argue that adding the word "about" into the claim would fail to inform a person of ordinary skill in the art about the scope of the claim with reasonable certainty, rendering the claim indefinite. (Def. Resp. Br. at 36). Because the sum of the intrinsic and extrinsic evidence indicates that the recited relative intensity values should be construed as "about" and the specification explains how "about" should be understood in the context of the invention, the Court will not rewrite the claim to preserve its validity. *Hill-Rom Servs., Inc.*, 755 F.3d at 1374. And while it is possible that the Court's construction may lead to issues with Claim 1's definiteness, the Court finds that such challenges can be better addressed with a more developed record. *See Alcon Research, Ltd.*, 2011 WL 3901878, at *16.

Finally, though Defendants argue that the recited 2theta values and relative intensity values should be construed as absolute, they also argue that it may be appropriate to construe the recited 2theta values and relative intensities to encompass any number that rounds up or down to those values. Thus, for example, they explain that a 2theta value of 5.32 would encompass values in the range of 5.315–5.324, which all round to 5.32, and a relative intensity value of 11% would include a range of 10.5% to 11.4%. (Def. Open. Br. at 38–39 n.4). Defendants argue that this is consistent with the approach taken in *AstraZeneca AB v. Mylan Pharms., Inc.*, 19 F.4th 1325, 1329 (Fed. Cir. 2021), where the court noted that using a range that encompasses values that round to 0.001% "'is a standard scientific convention, and numbers falling within that range would typically be rounded up or down to 0.001%.'" (Def. Open. Br. at 38). The Court declines to adopt such a construction.

To start, Defendants appear to misunderstand the Federal Circuit's holding in *AstraZeneca*. In *AstraZeneca*, the District Court initially construed the claim term "0.001%" of PVP to encompass a concentration of PVP in the range of "0.0005% to 0.0014%"—values that rounded

up and down to 0.001%. *AstraZeneca AB v. Mylan Pharm., Inc.*, No. 18-0193, 2020 WL 4670401, at * 7 (N.D.W. Va. Aug. 12, 2020). The Federal Circuit vacated this construction, recognizing that though 0.001% would ordinarily encompass a range from 0.0005% to 0.0014% that rounds up and down to 0.001% based on "standard scientific convention," the intrinsic evidence impacted the term's plain and ordinary meaning. *AstraZeneca AB v. Mylan Pharms.*, Inc., 19 F.4th 1325, 1329, 1335 (Fed. Cir. 2021). More specifically, the specification had emphasized the importance of the increased stability of the new compound to the claimed invention and "testing evidence in the written description and prosecution history show[ed] that very minor differences in the concentration of PVP—down to the ten thousandth of a percentage (fourth decimal place)—impact[ed] stability." *Id.* at 1330. The prosecution history also established that AstraZeneca had made significant amendments to the PVP concentration during patent prosecution. *Id.* at 1332–33. These amendments included exchanging a range of PVP concentration for the exact 0.001% value, eliminating the term "about" before the PVP concentration, and citing to testing establishing that variations in the PVP concentration to the fourth significant digit impacted the invention's stability. *Id.* at 1333–34. Thus, "taken as a whole, the intrinsic record support[ed] a narrower construction of 0.001%," and to "reflect[] the level of exactness the inventors used in the written description," the Federal Circuit construed 0.001% "as that precise number with only minor variations, i.e., 0.00095% to 0.00104%." *Id.* at 1330, 1334–35. Accordingly, the Federal Circuit expressly rejected interpreting "0.001%" in accordance with standard scientific convention, as Defendants appear to be asking the Court to do here. To the extent Defendants intend to rely on *Astrazeneca*, the intrinsic record in this case does not support such a similarly narrow construction of the recited 2theta values or relative intensity values because neither the specification nor prosecution history demonstrate that the inventors intended to impose such a precise level of

exactness for the recited values as the inventors did in *Astrazeneca*. Nevertheless, even if Defendants only advocate for a construction that incorporates values that round up and down to the recited 2theta values and relative intensity values according to standard scientific convention, an approach that was rejected by the court in *AstraZeneca* (*Markman* Hr'g Tr. at 143:6–22), the Court still finds that such a construction is not appropriate and would be unduly narrow. For all the reasons described above, the Court finds that the intrinsic and extrinsic record support construing both the recited 2theta values and relative intensity values as "about."

In sum, after considering claim context, the specification, the prosecution history, and the extrinsic evidence, and for all the foregoing reasons, the Court adopts Plaintiff's construction and construes "[C]haracteristic 2theta values at (relative intensity): 5.32 (11%), 5.78 (19%), 6.50 (27%), 7.24 (45%), 7.82 (61%), 8.80 (100%), 10.50 (59%), 11.02 (35%), 11.58 (32%), 13.08 (20%), 14.42 (26%), 17.32 (48%), 17.68 (93%), 18.58 (79%), 19.52 (61%), 21.04 (52%), 21.60 (30%), and 21.92 (46%)" to mean "characteristic 2theta values (relative intensity) at about: 5.32 (11%), 5.78 (19%), 6.50 (27%), 7.24 (45%), 7.82 (61%), 8.80 (100%), 10.50 (59%), 11.02 (35%), 11.58 (32%), 13.08 (20%), 14.42 (26%), 17.32 (48%), 17.68 (93%), 18.58 (79%), 19.52 (61%), 21.04 (52%), 21.60 (30%), and 21.92 (46%)."

7. *"[C]haracteristic 2theta values at: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92"* ('415 Patent, Claims 1, 9; '257 Patent, Claim 1)

Plaintiff	**Defendants**	**The Court**
"characterized by an X-Ray spectrum with characteristic 2theta values at about: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92."	"Plain and ordinary meaning, i.e., "characteristic 2theta values at: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92"	"characterized by an X-Ray spectrum with characteristic 2theta values at about: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92."

The disputed claim terms appear in Claims 1 and 9 of the '415 Patent, and Claim 1 of the '257 Patent and read as follows:

> ***'415 Patent*** Claim 1. A method of treating a subject suffering from traveler's diarrhea comprising: selecting a subject in need of treatment of traveler's diarrhea; administering to said subject a pharmaceutical composition comprising a therapeutically effective amount of Rifaximin in an α/β polymorphic mixture of 85/15±3 in an amount sufficient to treat the traveler's diarrhea, wherein the Rifaximin α/β polymorphic mixture is characterized by an X-Ray spectrum with characteristic 2theta values at: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92.
>
> ***'415 Patent*** Claim 9. A method of treating a subject suffering from hepatic encephalopathy comprising: selecting a subject in need of treatment of hepatic encephalopathy; administering to said subject a pharmaceutical composition comprising a therapeutically effective amount of Rifaximin in an α/β polymorphic mixture of 85/15±3 in an amount sufficient to treat the hepatic encephalopathy, wherein the Rifaximin α/β polymorphic mixture is characterized by an X-Ray spectrum with characteristic 2theta values at: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92.
>
> ***'257 Patent*** Claim 1. A Rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3, characterized by an X-Ray spectrum with characteristic 2theta values at: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92.

('415 Patent at 10:64–11:9 & 11:29–12:9; '257 Patent at 10:66–11:3). Because the specifications of the '415 Patent and '257 Patent are substantially the same as the '915 Patent specification, Plaintiff argues that the 2theta values recited in Claims 1 and 9 of the '415 Patent and Claim 1 of the '257 Patent should be construed consistent with the 2theta values recited in Claim 1 of the '915 Patent as "about." (Pl. Open. Br. at 37–38; Pl. Resp. Br. at 34–35). In contrast, Defendants argue that the 2theta values recited in Claims 1 and 9 of the '415 Patent and Claim 1 of the '257 Patent should be construed consistent with the 2theta values recited in Claim 1 of the '915 Patent as those

precise values, potentially subject to rounding. (Def. Open. Br. at 40; Def. Resp. Br. at 40). For the reasons set forth below, the Court adopts Plaintiff's construction.

The intrinsic and extrinsic evidence support construing the recited 2theta values in Claims 1 and 9 of the '415 Patent and Claim 1 of the '257 Patent as "about." With regards to the claim language itself, it is true that the Claims 1 and 9 of the '415 Patent and Claim 1 of the '257 Patent do not use words of approximation. However, as the parties point out, the '415 Patent specification and '257 Patent specification are substantially the same as the '915 Patent specification. Like the '915 Patent, the '415 Patent and '257 Patent explicitly provide:

> It is understood that all the values and intervals disclosed in the process of the present invention must not be intended as absolute. Any value or interval must be understood by the person of ordinary skill in the art as 'about.' The term 'about', as currently intended, means that any value herein disclosed not necessarily must be exactly taken per se, but that a deviation from this value is within the scope of the present invention, provided that the technical effect herein disclosed is achieved.

('415 Patent at 4:62–5:3; '257 Patent at 4:62–5:3). These portions of the specifications indicate that the inventors intended that *any value* disclosed in the '415 Patent and '257 Patent, including 2theta values, be construed as "about." Nevertheless, even if, as Defendants argue, these portions of the specifications only apply to values disclosed in the *process of the present invention*, they still, as discussed above, support construing the recited 2theta values in Claims 1 and 9 of the '415 Patent and Claim 1 of the '257 Patent as "about" because the specifications indicate that the recited 2theta values were disclosed in the process of the present invention. More specifically, after specifying that the values and intervals disclosed in the process of the present invention should not be intended as absolute, both the '415 Patent and '257 Patent describe a "preferred embodiment" of the process of the present invention that results in the final rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3. ('415 Patent at 5:4–46; '257 Patent at 5:4–46). At multiple

points during this process, the specifications describe intermediate products that are formed before the final rifaximin polymorphic mixture of α/β form. The specifications characterize those intermediate products by X-ray diffraction, indicating that X-ray diffraction is part of the process of the present invention. Because the 2theta values are obtained as a result of performing X-ray diffraction, the specifications of the '415 Patent and '257 Patent indicate that the 2theta values are themselves disclosed in the process of the present invention. As such, the specifications indicate that the 2theta values should be understood as "about." ('415 Patent at 5:4–46; '257 Patent at 5:4–46; *Markman* Hr'g Tr. at 94:22–95:15). Further, the final step of the process involves drying and then recovering a "Rifaximin α/β polymorphic mixture 85/15±3" "characterized by an X-Ray spectrum with characteristic 2theta values" as recited by Claims 1 and 9 of the '415 Patent and Claim 1 of the '257 Patent. ('415 Patent at 5:39–46 & '257 Patent at 5:39–46). As such, the final step of the "preferred embodiment" of the process of the present invention in the '415 Patent and '257 Patent involve recovering a "Rifaximin α/β polymorphic mixture" with characteristic 2theta values, indicating that those values are disclosed in the process of the present invention. Accordingly, the specifications of the '415 Patent and '257 Patent indicate that the inventors intended that the 2theta values recited in the patents be understood as "about," because those values were disclosed in the process of the present invention.

In addition, like the '915 Patent, the '415 Patent and '257 Patent disclose two figures, namely Figure 4 and Figure 5, which are also described in Examples 2 and 5 of the patents, which embody "[a] rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3," as disclosed by the inventions, and which each possess characteristic 2theta values that differ slightly. ('415 Patent at 5:39–46, 7:3–18, 8:54–9:27 & 10:48–63; '257 Patent at 5:39–46, 7:3–18, 8:54–9:27 & 10:48–63). As with the '915 Patent, Defendants' proposed construction of Claims 1 and 9

of the '415 Patent and Claim 1 of the '257 Patent would improperly exclude preferred embodiments of the present invention, as depicted in Figure 5 of both patents. Accordingly, because the specifications disclose variability in the 2theta values that correspond to "[a] rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3" of the invention, the specifications' disclosures indicate that the 2theta values recited in Claims 1 and 9 of the '415 Patent and Claim 1 of the '257 Patent should be construed as "about" rather than absolute.

In sum, because the '415 Patent specification and '257 Patent specification are substantially the same as the '915 Patent specification and similarly indicate that the recited 2theta values should be understood as about, and disclose variability in the 2theta values that correspond to "[a] rifaximin polymorphic mixture of α/β form in a relative ratio of 85/15±3" of the invention the Court finds that, for the same reasons set forth above in Section III(C)(b)(6), with respect to 2theta values specifically,[25] the 2theta values as recited in Claims 1 and 9 of the '415 Patent and Claim 1 of the '257 Patent, like Claim 1 of the '915 Patent, should be construed as "about."[26]

Further, the extrinsic evidence is consistent with the intrinsic evidence and supports construing the 2theta values in Claims 1 and 9 of the '415 Patent and Claim 1 of the '257 Patent as "about" given that the USP provides that when using XRPD to compare a known material ("reference") with an unknown material ("specimen"): "[t]he agreement in the 2[theta]-diffraction angles between specimen and reference is within 0.2° for the *same crystal form*." (USP 941 at 507). As such, for the same reasons set forth above in Section III(C)(b)(6), the Court construes

[25] Unlike Claim 1 of the '915 Patent, Claims 1 and 9 of the '415 Patent and Claim 1 of the '257 Patent do not recite relative intensity values. As such, in construing Claims 1 and 9 of the '415 Patent and Claim 1 of the '257 Patent, the Court adopts the reasoning it employed in construing the 2theta values of Claim 1 of the '915 Patent specifically. *Samsung Elecs. Co.*, 925 F.3d at 1378.

[26] The Court also reaches this conclusion after considering the prosecution history of the '915 Patent, which is relevant in construing terms in the '415 Patent and '257 Patent—members of the same patent family. *Capital Mach. Co.*, 524 Fed. App'x at 649.

"[C]haracteristic 2theta values at: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92" in Claims 1 and 9 of the '415 Patent and Claim 1 of the '257 Patent to mean "characterized by an X-Ray spectrum with characteristic 2theta values at about: 5.32, 5.78, 6.50, 7.24, 7.82, 8.80, 10.50, 11.02, 11.58, 13.08, 14.42, 17.32, 17.68, 18.58, 19.52, 21.04, 21.60, and 21.92."

IV. CONCLUSION

The Court will construe the disputed terms as explained above. An appropriate Order follows.

Dated: January 26, 2024

s/ Esther Salas
Esther Salas, U.S.D.J.